

# ORDER FOR SUPPLIES OR SERVICES

PAGE OF PAGES

1

4

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER 02/11/2021		2. CONTRACT NO. (If any) 68HERC19D0011		6. SHIP TO: a. NAME OF CONSIGNEE Multiple Destinations	
3. ORDER NO. 68HERC21F0115		4. REQUISITION/REFERENCE NO. See Schedule			
5. ISSUING OFFICE (Address correspondence to) CAD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001				b. STREET ADDRESS	
				c. CITY	e. ZIP CODE
7. TO: JAMES BURKE a. NAME OF CONTRACTOR National Academy of Sciences b. COMPANY NAME				f. SHIP VIA	
c. STREET ADDRESS 500 FIFTH STREET NW				8. TYPE OF ORDER <input type="checkbox"/> a. PURCHASE <input checked="" type="checkbox"/> b. DELIVERY REFERENCE YOUR:  Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.	
d. CITY WASHINGTON		e. STATE DC	f. ZIP CODE 200012736	Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.	
9. ACCOUNTING AND APPROPRIATION DATA See Schedule				10. REQUISITIONING OFFICE Office of Research and Development	

11. BUSINESS CLASSIFICATION (Check appropriate box(es)) <input type="checkbox"/> a. SMALL <input checked="" type="checkbox"/> b. OTHER THAN SMALL <input type="checkbox"/> c. DISADVANTAGED <input type="checkbox"/> d. WOMEN-OWNED <input type="checkbox"/> e. HUBZone <input type="checkbox"/> f. SERVICE-DISABLED VETERAN-OWNED <input type="checkbox"/> g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM <input type="checkbox"/> h. EDWOSB				12. F.O.B. POINT	
13. PLACE OF a. INSPECTION Destination		b. ACCEPTANCE Destination		14. GOVERNMENT B/L NO.	
				15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 07/10/2022	
				16. DISCOUNT TERMS	

## 17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	DUNS Number: 041964057 TOCOR: EMILY SNYDER Max Expire Date: 07/10/2022  Continued ...					

SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT		19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		17(h) TOTAL (Cont. pages)
	21. MAIL INVOICE TO:						
	a. NAME RTP Finance Center						\$268,221.00
	b. STREET ADDRESS (or P.O. Box) US Environmental Protection Agency RTP-Finance Center (AA216-01) 109 TW Alexander Drive www2.epa.gov/financial/contracts						\$268,221.00
c. CITY Durham			d. STATE NC	e. ZIP CODE 27711		17(i) GRAND TOTAL	

22. UNITED STATES OF AMERICA BY (Signature) 02/11/2021

ELECTRONIC  
SIGNATURE

23. NAME (Typed)  
William M. Yates  
TITLE: CONTRACTING/ORDERING OFFICER

**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

PAGE NO  
2

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 02/11/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0115
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
0001	Admin Office: CAD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001  COVID-Related Funds from CPHEA IO (\$7,300) Funds from IA HQ11920074859 - RW019925406 (\$258,221) New Task Order (\$258,221) New Task Order Request under NAS Contract #68HERC19D0011 (CPHEA) Titled: Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces. Task Order #: TBD Title: Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces CO: Mark Cranley CS: William Yates Acquisition Division: CAD Exception Code (5170 Conference Process): ME262600 TOCOR: Emily Snyder ALTOCOR: David Lehmann CL COR: Glennis Reslock ALT CL COR: Jorge Rangel No IT Codes or FITARA necessary  Requisition No: PR-ORD-21-00363  Delivery Location Code: ORD RTP Office of Research and Development US Environmental Protection Agency 109 T.W. Alexander Drive Research Triangle Park NC 27711 Amount: \$258,221.00 Accounting Info: 21-22-CR-26D2X05-000FK6XR2-2532-26A5C- 2126D2C006-001 BFY: 21 EFY: 22 Fund: CR Budget Org: 26D2X05 Program (PRC): 000FK6XR2 Budget (BOC): 2532 Cost: 26A5C DCN - Line ID: 2126D2C006-001 Continued ...					
					258,221.00	

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$258,221.00



**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

PAGE NO  
3

**IMPORTANT:** Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 02/11/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0115
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
0002	Funding Flag: Complete Funded: \$258,221.00  COVID-related Funds from CPHEA IO (\$7,300) Funds from IA HQ11920074859 - RW019925406 (\$258,221) New Task Order (\$258,221) New Task Order Request under NAS Contract #68HERC19D0011 (CPHEA) Titled: Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces. Task Order #: TBD Title: Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces CO: Mark Cranley CS: William Yates Acquisition Division: CAD Exception Code (5170 Conference Process): ME262600 TOCOR: Emily Snyder ALTOCOR: David Lehmann CL COR: Glennis Reslock ALT CL COR: Jorge Rangel No IT Codes or FITARA necessary  Requisition No: PR-ORD-21-00363  Delivery Location Code: ORD RTP Office of Research and Development US Environmental Protection Agency 109 T.W. Alexander Drive Research Triangle Park NC 27711 Amount: \$7,300.00 Accounting Info: 21-22-C-26DD000-000FK8XPV-2532-26A5C-2 126D2C006-002 BFY: 21 EFY: 22 Fund: C Budget Org: 26DD000 Program (PRC): 000FK8XPV Budget (BOC): 2532 Cost: 26A5C DCN - Line ID: 2126D2C006-002 Funding Flag: Complete Funded: \$7,300.00			7,300.00		
0003	Funds from OAR OAQPS \$2700/Susan Stone/HEID Continued ...				2,700.00	
TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))					\$10,000.00	

**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

PAGE NO  
4

**IMPORTANT:** Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 02/11/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0115
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
New Task	<p>- FABS#PR-0014131/HEID Admin Funds</p> <p>Order Request under NAS Contract  #68HERC19D0011 (CPHEA) Titled: Respiratory  Protection for the Public and Workers  without Respiratory Protection Programs at  their Workplaces; Task Order #: TBD  Title: Respiratory Protection for the  Public and Workers without Respiratory  Protection Programs at their Workplaces  CO: Mark Cranley;  CS: William Yates  Exception Code (5170 Conference Process):  ME262600  TOCOR: Emily Snyder;  ALTOCOR: David Lehmann;  CL COR: Glennis Reslock;  ALT CL COR: Jorge Rangel  Please also see ORD-21-00363 for funds to  cover new task order  Requisition No: PR-OAR-21-00336</p> <p>Delivery Location Code: OAR/OAQPS/CORE  OAR/OAQPS/CORE  US Environmental Protection Agency  Mail Code: C404-02  109 TW Alexander Drive  Durham NC 27711 USA  Amount: \$2,700.00  Accounting Info:  20-21-B-53I3-000A46-2505-ME262600-2153  IP1014-001 BFY: 20 EFY: 21 Fund: B  Budget Org: 53I3 Program (PRC):  000A46 Budget (BOC): 2505 Job #:  ME262600 DCN - Line ID: 2153IP1014-001  Funding Flag: Complete  Funded: \$2,700.00</p>					

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$0.00

## PERFORMANCE WORK STATEMENT

National Academy of Sciences (NAS)

Contract #68HERC19D0011

PR-ORD-21-00363 and PR-OAR-21-00336

Task Order #68HERC21F0115

**I. TITLE:** Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces

**EAS Short Title:** Respiratory Protection for the Public and Workers

### II. Task Order Contracting Officer Representative(s):

<b>Task Order Contracting Officer Representative (TOCOR)</b> <b>Name:</b> Emily Snyder <b>Office:</b> ORD/CPHEA/HEEAD/IO U.S. EPA, 109 T.W. Alexander Drive Mail Code: D143-01, Room #D1401 Research Triangle Park, NC 27711  <b>Phone:</b> 919-541-1006 <b>Email:</b> <a href="mailto:snyder.emily@epa.gov">snyder.emily@epa.gov</a>	<b>Alternate Task Order Contracting Officer Representative (ALTOCOR)</b> <b>Name:</b> David Lehmann <b>Office:</b> ORD/CPHEA/HEEAD/IHAB U.S. EPA, 109 T.W. Alexander Drive Mail Code: B105-02, Room #B487 Research Triangle Park, NC 27711  <b>Phone:</b> 919-541-0234 <b>Email:</b> <a href="mailto:lehmann.david@epa.gov">lehmann.david@epa.gov</a>
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**III. PERIOD OF PERFORMANCE:** Date of Task Order award 2/11/2021 through 7/10/2022.

### IV. PURPOSE OF TASK ORDER

The purpose of this task order (TO) is to conduct a study organized by a committee of scientific experts and leaders convened by the National Academies of Sciences (NAS) to examine and consider processes for ensuring effective and appropriate respiratory protection for the general public when faced with inhalation hazards, including those associated with severe air pollution, wildfires, pandemics such as COVID-19, and other disasters and public health emergencies. The study will specifically address respiratory protection needs for vulnerable populations such as children, the elderly, and people with respiratory or cardiovascular disease. Additionally, respiratory protection issues will be explored for a broad range of workers who may need to use respiratory protective devices but whose workplaces are not required to implement respiratory protection programs.

### V. BACKGROUND

In the United States (U.S.), the testing and approval of respirators for worker safety and health and post-approval issues are under the purview of the National Institute for Occupational Safety

and Health (NIOSH) and its National Personal Protective Technology Laboratory (NPPTL). The respirator approval process is limited to respirators for occupational use. Currently no respirators are approved for use by the general public during an environmental disaster (e.g. wildfires, severe air pollution) or pandemic (such as COVID-19) and there is not an approval process or central communication authority regarding respiratory protection for the general public for non-occupational use. Recent air quality concerns in the U.S. have included the widespread wildfires in California. In addition, air pollution levels are faced by embassy staff and families living abroad in high pollution areas including in China, India, and Indonesia. The respiratory protection needs of a broader class of workers who typically do not have respiratory protection programs in place also need to be addressed. Further, there are specific issues of concern regarding respiratory protection of vulnerable populations including children, the elderly, and people with respiratory or cardiovascular disease.

EPA conducts research on air pollutants and sets national ambient air quality standards subsequent to its authority under the Clean Air Act. In the U.S., particulate matter (airborne particles less than 2.5 micron in diameter, termed PM<sub>2.5</sub>) is the most significant cause of air pollution-related health effects. Additionally, EPA is concerned about the public health impacts of PM<sub>2.5</sub> in wildfire smoke, as wildfires have been steadily increasing in frequency and magnitude. EPA, jointly with its interagency collaborators, recommends the use of respiratory protection by the general public during wildfires. However, many questions remain to be addressed about effective respiratory protection for the public and workers who are not covered by respiratory protection programs. The U.S. Department of State (DOS) and specifically, the Overseas Buildings Operations Bureau's Office of Safety, Health and Environmental Management (OBO/OPS/SHEM) require technical expertise to advise on the use of respiratory protection by overseas family members including children. Severe air pollution at most overseas locations is a major driver for use of respirators of varying degrees of quality and fit by family members. Other scenarios for use include wildfires, volcanic eruptions, chemical/biological attacks, and pandemics.

EPA and DOS have the following questions related to respiratory protection for the general public.

- What are the specific situations/scenarios that impact air quality outside traditional workplaces, which trigger the need for respiratory protection, e.g., forest fires, air pollution, chemical factory exhausts or accidents?
- What steps/actions do agencies and governments take at the local, state, and federal levels to help the affected populations on respiratory protection, e.g., relief workers, diplomats, general public? Examples of agencies and organizations include county/state health departments, FEMA, EPA, DOS, and nonprofits, such as the American Red Cross.
- What resources are currently available to such agencies and organizations to guide the affected populations (e.g., relief workers, diplomats, general public) about effective measures for respiratory protection? What are the existing specific sources (e.g., government agencies, manufacturers) of information on respiratory protection?
- What are the respiratory protection needs for vulnerable populations (e.g., children, the elderly, and respiratory-compromised individuals)? What considerations are needed

regarding the regulatory implications and approval processes for respiratory protective devices for these populations?

- What is the current role of each involved federal agency and what specific actions does it take in responding to inquiries or requests for guidance from other agencies and the general public? Do the current infrastructure, processes, and resources in place at any of the organizations facilitate optimal and effective guidance in responding to such inquiries? What, if any, are the barriers?
- What is the most effective way for a federal organization to serve as the authoritative and unified source of information and guidance to ensure the respiratory health and safety of the Nation and to ensure that respiratory protective devices meet the needs of all workers and the general public?
- What changes or enhancements must be made in the following areas to fulfill this responsibility?
  - Policies governing its charter
  - Organizational structure
  - Operations
  - Resources: Financial and Human
  - Communications and Outreach to a broader audience that includes the general public
- What is a reasonable timeline to establish this responsibility in a federal organization?

## **VI. SCOPE OF WORK**

Per request from federal agencies across the U.S. government, the National Academies of Sciences, Engineering, and Medicine (NASEM) is convening an expert ad hoc committee that includes membership of the National Academies, relevant organizations and associations, federal agencies, and other experts in the areas to be addressed in the study. The committee was selected to ensure the presence of individuals with expertise in a variety of fields, including respiratory health, physiology, public health, occupational safety and health, emergency planning, respirator manufacturing, respirator research and evaluation, industrial hygiene, safety technology, worker advocacy, regulatory policy, and communications. The consensus report should be organized to address the following objectives:

- 1) determine the need for guidance on respiratory protection for the general public (including children and adults) and workers facing inhalation hazards outside of workplaces with known respiratory hazards subject to requirements for respiratory protection programs, including during disasters and public health emergencies. This should be based on an assessment of existing knowledge regarding the necessary factors (e.g. fit, filtration, fabric, airflow, and leakage) to ensure respiratory protection is effective for its intended use (i.e., source control and/or protection) across different hazard scenarios and the identification of gaps in existing standards/guidance;

- 2) describe current and potential options for oversight and approval of respirators for these populations (i.e., workers who may need to use respiratory protective devices in the absence of a respiratory protection program and the general public); and
- 3) make recommendations for a framework of responsibilities and authorities, including those of federal agencies, to provide a unified and authoritative source of information and effective oversight in the development, approval, and use of respirators, including conformity assessment processes to meet the needs of these populations.

Through this task order, EPA and DOS will fund this study. By funding this study, the two agencies' equities will be considered. Both EPA and DOS have stakeholders using respirators during emergencies and EPA, as the agency responsible for protecting human health from environmental hazards, will benefit from expert advice on developing guidance for the public about use of devices and other steps to provide respiratory protection.

## **VII. DESCRIPTION OF TASKS**

### **Task 1: Kick-off Call (Contract Level PWS, Task Area 2, Page 5)**

The NASEM shall convene a teleconference with the TOCOR and relevant EPA staff to review the deliverables and communication plans. This teleconference shall occur within seven (7) days after NASEM acceptance of the TO.

#### ***Task 1. Deliverables***

<b>Task</b>	<b>Sub-Task</b>	<b>Deliverable</b>	<b>Schedule</b>
1	NA	Kick-off Call	Within seven (7) days after NASEM acceptance of the TO.

### **Task 2: Committee Membership (Contract Level PWS, Task Area 2, Page 5)**

NASEM put together an expert ad hoc committee that includes membership of the National Academies, relevant organizations and associations, federal agencies, and other experts in the areas to be addressed in the study. NASEM shall provide a final list of committee members that includes biographical sketches which indicate their areas of expertise.

<b>Task</b>	<b>Sub-Task</b>	<b>Deliverable</b>	<b>Schedule</b>
2	NA	List of committee members and biographical sketches	Within fifteen (15) days of award of task order.

### **Task 3: Committee Meetings (Contract Level PWS, Task Area 2, Page 5 & Task Area 5 Page 6)**

EPA is requesting NASEM to conduct virtual meetings. Typically, these committee meeting are held in person but due to COVID-19, EPA is anticipating that two (2) will be held virtually with the possibility of one (1) being held in-person.

The committee shall hold two (2) virtual meetings and one (1) in-person meeting, each having a public portion where they gather information from relevant experts and other stakeholders that shall inform their consensus report. NASEM shall identify expert speakers to participate in the public portion. NASEM shall set up and manage the virtual and in-person meetings and provide any technical support for the committee and the external experts' participation. The TOCOR and ALTOCOR shall be informed via email of the date, time, and agenda of virtual meeting and in-person meeting at least one (1) month prior to the meetings. All communications regarding the virtual meetings should go through the TOCOR and ALTOCOR.

### ***Task 3. Deliverables***

<b>Task</b>	<b>Sub-Task</b>	<b>Deliverable</b>	<b>Schedule</b>
3	NA	Date, time, and agenda of meetings.	One (1) month prior to the meetings.

### **Task 4: Draft and Release of Consensus Study Report Respiratory Protection for the General Public (Contract Level PWS, Task Area 2, Page 5)**

EPA is requesting NASEM to produce a consensus study report on Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces.

#### ***Sub-Task 4.1 Drafting and Peer-Review of Consensus Study Report***

The committee shall produce a consensus study report documenting the respiratory protection for the public and workers without respiratory protection programs at their workplaces, consistent with the scope of work/study charge as described in section VI. The committee shall determine the need for guidance on respiratory protection for the general public, describe current potential options for oversight and approval of respirators for these populations, and make recommendations for a framework of responsibilities and authorities, including which federal agencies should ultimately be responsible. Before release, the committee's report is subject to the NAS's review procedures before it is delivered to EPA. EPA will share the report with DOS.

#### ***Sub-Task 4.2 Creation of Webpage to Disseminate Consensus Report Information***

The NASEM shall create a NASEM webpage for dissemination of information about the report prior to posting of the pre-publication version of the consensus report. The TOCOR and ALTOCOR shall be notified via email of the location of this website or similar means used to disseminate information to the public during the course of this task, as well as relevant changes to them.

***Sub-Task 4.3: Pre-release briefing for EPA and DOS on Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces Consensus Report***

NASEM shall provide a briefing for senior leadership in EPA, DOS, and other government agencies on the report Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces, including participation from the Committee members, prior to the posting of the pre-publication consensus study report on the NASEM Website. The briefing should occur no later than 14 days prior to the pre-publication consensus study report on NASEM Website.

***Sub-Task 4.4 Pre-publication Consensus Study Report on NASEM Website***

Once finalized and approved by the NASEM, the report shall be released as a pre-publication Adobe PDF download to the public via the NASEM website. The TOCOR and ALTOCOR shall be notified via email of the location of posting of the report on the NASEM website developed under Sub-Task 4.2.

***Sub-Task 4.5 Final Consensus Study Report on NASEM Website and in Print***

Within one month of the pre-publication release, two final edited and bound versions of the report shall be available in print and Adobe PDF download via the NASEM website. The committee shall use the National Academies Projects and Activities Repository (NAPAR) on the National Academies' website to post information, as appropriate, under its procedures that implement the requirements of Federal Advisory Committee Act (FACA) Section 15. The TOCOR and ALTOCOR shall be notified via email of posting of the report on the NASEM website for the report.

<b>Task</b>	<b>Sub-Task</b>	<b>Deliverable</b>	<b>Schedule</b>
4	4.1	Conduct Peer-Review of Consensus Study Report	At least four (4) months prior to the end of the task order.
4	4.2	Webpage to Disseminate Consensus Report Information	Prior to completion of Sub-Task 4.4.
4	4.3	Pre-release briefing for EPA and DOS on Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces Consensus Report	At least fourteen (14) days prior to completion of Sub-Task 4.3.
4	4.4	Pre-publication Consensus Study Report on NASEM Website	At least three (3) months prior to the expiration of the task order.
4	4.5	Final Consensus Study Report on NASEM Website and in Print	Within one month of the pre-publication release.



**Task 5: Dissemination of Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces (Contract Level PWS Task Area 2)**

***Sub-Task 5.1: Report Highlights for Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces Consensus Report***

The NASEM shall create a 3-8 page document that includes report highlights and list of recommendations based on the findings in the consensus study report. The target audience for the report highlights and the list of recommendations is the EPA, DOS, other government agencies, and Congressional members and staff. This document may be in the form of a text summary, graphical summary, or some combination of both. It shall also be released as an Adobe PDF download to the public via the NASEM website created for this report.

***Sub-Task 5.2: Public Webinar on Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces Consensus Report***

The NASEM shall conduct a public webinar on the consensus report. The TOCOR and ALTOCOR shall be informed via email of the date, time of the webinar at least one (1) month prior to the events. At least one (1) month prior to the end of the task order NASEM shall conduct the webinar. All communications regarding the public webinar should go through the TOCOR and ALTOCOR.

***Sub-Task 5.3: Recording the Public Webinar on Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces Consensus Report***

The public webinar conducted under Sub-Task 5.2 shall be recorded and made available on the NASEM website. The TOCOR and ALTOCOR shall be notified when the recording is posted and any additional means used to disseminate information on the webinar recording to the public during the course of this task, as well as relevant changes to them.

***Sub-Task 5.4: Congressional Briefings on Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces Consensus Report***

NASEM shall provide two briefings to Congressional members and staff. This briefing shall include participation from the Committee members. The TOCOR and ALTOCOR shall be informed via email of the date, time, and agenda of the briefings at least fourteen days prior to the briefings.

<b>Task</b>	<b>Sub-Task</b>	<b>Deliverable</b>	<b>Schedule</b>
5	5.1	Report Highlights	At least two (2) months prior to the expiration of the task order.
5	5.2	Date and time of Public Webinar	At least one (1) month prior to webinar.

5	5.2	Public Webinar	At least one (1) month prior to the expiration of the task order.
5	5.3	Recordings of Public Webinar available on the NASEM website	At least fourteen (14) days prior to the expiration of the task order.
5	5.4	Date and time of Congressional Briefings	At least fourteen (14) days prior to the briefings.
5	5.4	Two (2) Congressional Briefings on Respiratory Protection for the Public and Workers without Respiratory Protection Programs at their Workplaces Consensus Report	At least one (1) month prior to the expiration of the task order.

## VIII. ACCEPTANCE CRITERIA

The Contractor shall prepare high quality products and that are reproducible and transparent. Figures submitted shall be of high quality similar to presentations developed for national scientific forums and should be formatted as jpeg or TIFF files. Deliverables shall be edited for grammar, spelling, and logic flow, as well as, technical accuracy, completeness, timeliness, grammatically correct, free of typographical errors, and conformance with the specific task, charge and expertise and deliverables of this Performance Work Statement. The technical information shall be reasonable complete and presented in a logical, readable manner. Text deliverables shall be provided in Microsoft Word 2016 and Adobe Acrobat. Deliverables will be accepted upon review and approval by the TOCOR.

# ORDER FOR SUPPLIES OR SERVICES

PAGE OF PAGES

1

5

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER 03/23/2021		2. CONTRACT NO. (If any) 68HERC19D0011		6. SHIP TO: a. NAME OF CONSIGNEE Office of Research and Development	
3. ORDER NO. 68HERC21F0178		4. REQUISITION/REFERENCE NO. See Schedule			
5. ISSUING OFFICE (Address correspondence to) CAD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001				b. STREET ADDRESS US Environmental Protection Agency 109 T.W. Alexander Drive	
				c. CITY Research Triangle Park	e. ZIP CODE 27711
7. TO: JAMES BURKE				f. SHIP VIA	
a. NAME OF CONTRACTOR National Academy of Sciences				8. TYPE OF ORDER	
b. COMPANY NAME				<input type="checkbox"/> a. PURCHASE <input checked="" type="checkbox"/> b. DELIVERY REFERENCE YOUR: _____ Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.	
c. STREET ADDRESS 500 FIFTH STREET NW				Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.	
d. CITY WASHINGTON		e. STATE DC	f. ZIP CODE 200012736		
9. ACCOUNTING AND APPROPRIATION DATA See Schedule				10. REQUISITIONING OFFICE Office of Research and Development	

11. BUSINESS CLASSIFICATION (Check appropriate box(es)) <input type="checkbox"/> a. SMALL <input checked="" type="checkbox"/> b. OTHER THAN SMALL <input type="checkbox"/> c. DISADVANTAGED <input type="checkbox"/> d. WOMEN-OWNED <input type="checkbox"/> e. HUBZone <input type="checkbox"/> f. SERVICE-DISABLED VETERAN-OWNED <input type="checkbox"/> g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM <input type="checkbox"/> h. EDWOSB				12. F.O.B. POINT	
13. PLACE OF a. INSPECTION Destination		b. ACCEPTANCE Destination		14. GOVERNMENT B/L NO.	
				15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 03/22/2023	
16. DISCOUNT TERMS					

## 17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	DUNS Number: 041964057 TOCOR: ALEXANDER HANF Max Expire Date: 03/22/2023  Continued ...					

SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT		19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		17(h) TOTAL (Cont. pages)
	21. MAIL INVOICE TO:						
	a. NAME RTP Finance Center						\$990,257.00
	b. STREET ADDRESS (or P.O. Box) US Environmental Protection Agency RTP-Finance Center (AA216-01) 109 TW Alexander Drive www2.epa.gov/financial/contracts						\$990,257.00
c. CITY Durham				d. STATE NC	e. ZIP CODE 27711		17(i) GRAND TOTAL

22. UNITED STATES OF AMERICA BY (Signature) 03/23/2021

ELECTRONIC SIGNATURE

23. NAME (Typed)  
William M. Yates  
TITLE: CONTRACTING/ORDERING OFFICER

## ORDER FOR SUPPLIES OR SERVICES

PAGE NO

## SCHEDULE - CONTINUATION

2

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 03/23/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0178
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
0002	Admin Office: CAD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001 Period of Performance: 03/23/2021 to 03/21/2023  De-obligate funding in the amount of \$209,338.17 for a grand total of \$740,257.00				990,257.00	
2126RRC008	New Task Order Contract #68HERC19D0011 Task Order #: TBD Title: Variability and Relevance of Current Laboratory Mammalian Toxicity Tests and Expectations for New Approach Methods (NAMs) for use in Human Health Risk Assessment CO: Mark Cranley CS: William Yates, Contract Specialist Acquisition Division: CAD Exemption Code (5170 Conference Process): ME262600 TOCOR: Alexander Hanf ALTOCOR: James Noel CL COR: Glennis Reslock ALT CL COR: Jorge Rangel No IT Codes or FITARA necessary  The following PR's must be included in this new TO request for a grand total of: \$990,257.00 PR-ORD-21-00431 CTE \$740,257.00 PR-OCSPP-21-00045 OCSPP \$250,000.00 (EDSP funds) Requisition No: PR-OCSPP-21-00045, PR-ORD-21-00431  Accounting Info: 20-21-C-26RR000-000F72XPC-2532-26A5C-2 126RRC008-001 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000F72XPC Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-001 Continued ...					
TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))					\$990,257.00	

**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

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**IMPORTANT:** Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 03/23/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0178
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Funding Flag: Partial Funded: \$2,433.00 Accounting Info: 20-21-C-26RR000-000F84-2532-26A5C-2126 RRC008-002 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000F84 Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-002 Funding Flag: Partial Funded: \$19,195.17 Accounting Info: 20-21-C-26RR000-000FK6XR1-2532-26A5C-2 126RRC008-003 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000FK6XR1 Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-003 Funding Flag: Partial Funded: \$110,934.00 Accounting Info: 20-21-C-26RR000-000FK6XR2-2532-26A5C-2 126RRC008-004 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000FK6XR2 Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-004 Funding Flag: Partial Funded: \$114,597.00 Accounting Info: 20-21-C-26RR000-000FK7XR3-2532-26A5C-2 126RRC008-005 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000FK7XR3 Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-005 Funding Flag: Partial Funded: \$32,258.00 Accounting Info: 20-21-C-26RR000-000FK7XR4-2532-26A5C-2 126RRC008-006 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000FK7XR4 Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-006 Funding Flag: Partial Continued ...					

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$0.00

**ORDER FOR SUPPLIES OR SERVICES**  
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IMPORTANT: Mark all packages and papers with contract and/or order numbers.

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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Funded: \$11,265.00 Accounting Info: 20-21-C-26RR000-000FK8-2532-26A5C-2126 RRC008-007 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000FK8 Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-007 Funding Flag: Partial Funded: \$38,410.00 Accounting Info: 20-21-C-26RR000-000FK8XPV-2532-26A5C-2 126RRC008-008 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000FK8XPV Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-008 Funding Flag: Partial Funded: \$35,500.00 Accounting Info: 20-21-C-26RR000-000FK8XPW-2532-26A5C-2 126RRC008-009 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000FK8XPW Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-009 Funding Flag: Partial Funded: \$81,129.00 Accounting Info: 20-21-C-26RR000-000FK9-2532-26A5C-2126 RRC008-010 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000FK9 Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-010 Funding Flag: Partial Funded: \$38,890.00 Accounting Info: 20-21-C-26RR000-000FK9XR5-2532-26A5C-2 126RRC008-011 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000FK9XR5 Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-011 Funding Flag: Partial Funded: \$151,064.00 Continued ...					

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$0.00

**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

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**IMPORTANT:** Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 03/23/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0178
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Accounting Info: 20-21-C-26RR000-000FK9XR6-2532-26A5C-2 126RRC008-012 BFY: 20 EFY: 21 Fund: C Budget Org: 26RR000 Program (PRC): 000FK9XR6 Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-012 Funding Flag: Partial Funded: \$71,737.00 Accounting Info: 21-22-C-26RR000-000FK6XR2-2532-26A5C-2 126RRC008-013 BFY: 21 EFY: 22 Fund: C Budget Org: 26RR000 Program (PRC): 000FK6XR2 Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-013 Funding Flag: Partial Funded: \$0.00 Accounting Info: 21-22-C-26RR000-000FK7XR4-2532-26A5C-2 126RRC008-014 BFY: 21 EFY: 22 Fund: C Budget Org: 26RR000 Program (PRC): 000FK7XR4 Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-014 Funding Flag: Partial Funded: \$0.00 Accounting Info: 21-22-C-26RR000-000FK8XPV-2532-26A5C-2 126RRC008-015 BFY: 21 EFY: 22 Fund: C Budget Org: 26RR000 Program (PRC): 000FK8XPV Budget (BOC): 2532 Job #: ME262600 Cost: 26A5C DCN - Line ID: 2126RRC008-015 Funding Flag: Partial Funded: \$32,844.83 Accounting Info: 21-22-B-32D-000C54-2505-2132HED027-001 BFY: 21 EFY: 22 Fund: B Budget Org: 32D Program (PRC): 000C54 Budget (BOC): 2505 Job #: QF320513 DCN - Line ID: 2132HED027-001 Funding Flag: Partial Funded: \$250,000.00					

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$0.00

Performance Work Statement  
National Academy of Sciences (NAS)  
Contract #68HERC19D0011  
PR-ORD-21-00431  
PR-OCSP-21-00045  
Task Order: #68HERC21F0178

**I. TITLE:** Variability and Relevance of Current Laboratory Mammalian Toxicity Tests and Expectations for New Approach Methods (NAMs) for use in Human Health Risk Assessment

**II. Task Order Contracting Officer Representative(s):**

<b>Task Order Contracting Officer Representative (TOCOR)</b> <b>Name:</b> Alexander Hanf <b>Office:</b> CCTE/CRPIS U.S EPA 109 T.W. Alexander Drive Mail Code: D143-02 RTP, NC 27711  Telephone: 919-541-2750 E-mail: hanf.alexander@epa.gov	<b>Alternate Task Order Contracting Officer Representative (Alt. TOCOR)</b> <b>Name:</b> James Noel <b>Office:</b> CCTE/CRPIS U.S EPA 109 T.W. Alexander Drive Mail Code: D343-05 RTP, NC 27711  Telephone: 919-541-1051 E-mail: noel.james@epa.gov
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**III. PERIOD OF PERFORMANCE:** Date of Task Order award through 24 months following award

**A. PURPOSE OF TASK ORDER**

The National Academy of Sciences (NAS) shall provide the Environmental Protection Agency (EPA) with a review of the variability and relevance of existing laboratory mammalian toxicity tests for human health risk assessment to inform the development of approaches for validation and establishing scientific confidence in using New Approach Methods (NAMs), and recommendations on expectations associated with NAMs when they cannot be compared with human studies, by hosting two (2) workshops and establishing an expert committee, described in the Scope of Work and Tasks 1-4 below.

**B. BACKGROUND**

In 2017, National Research Council (NRC) released a report entitled “Using 21st Century Science to Improve Risk-Related Evaluations.” The risk-related applications report highlighted both the progress that had occurred in toxicology and exposure sciences since the release of previous



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reports and identified several decision contexts that could benefit from application of the advances in the fields. It proposed a shift in thinking of the risk assessment community from whether a chemical causes a particular effect to whether a chemical increases the risk of a particular effect, while also recognizing that one does not need to know all the pathways or components involved in a particular disease to begin applying the new tools to regulatory decisions. The NRC Committee on Incorporating 21st Century Science into Risk-Based Evaluations also touched on the subject of validation and that many of the traditional processes for validation cannot match the pace of development of new assays, models, and test systems. The report recognized the challenges in validating a NAM where there is no “gold standard” or against toxicity tests that have not themselves been validated. The NRC Committee highlighted that there were two important issues on which there was still no consensus in the scientific community: 1) evaluation of the validity of assays that are not intended as one-to-one replacements for *in vivo* toxicity assays; and 2) assessment of the concordance of data from assays that use cells or proteins of human origin with toxicity data that are virtually all derived from animal models.

One of the important considerations in the evaluation of ‘equivalent or better’ approaches is that laboratory mammalian toxicity data provide a part of the foundation of the current risk assessment paradigm, and mammalian studies often provide the only available *in vivo* data for many environmental chemicals. There are a number of new evaluations of the qualitative and quantitative variability (Kleinstreuer *et al.*, 2016; Browne *et al.*, 2018; Pham *et al.*, 2020) and human relevance (e.g., Monticello *et al.*, 2017; Hoffmann *et al.*, 2018; Ackley *et al.*, 2019), of laboratory mammalian toxicity studies. These new studies highlight some of the limitations and challenges associated with using laboratory mammalian toxicity data as the standard benchmark for evaluating and implementing NAMs. Since the 2017 NRC report on 21<sup>st</sup> Century risk-related evaluations, the state of the science has continued to progress and the understanding and experience with NAMs has led to new considerations and more focused scientific questions. EPA is soliciting support from NAS to explore the strengths and limitations of using laboratory mammalian toxicology data as the benchmark for developing and evaluating NAMs, as well as possible novel approaches to validation and confidence building in using NAMs to replace mammalian toxicology data. This scientific exploration will become important in the policy decisions that EPA needs to address with “validation to ensure that NAMs are equivalent to or better than the animal tests replaced.”

## C. SCOPE OF WORK

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The NAS shall provide the EPA with a mechanism to recruit NAS identified subject-matter experts and when necessary, provide a forum for discussion(s) on science topics pertinent to using laboratory animal toxicology data as the benchmark for developing and evaluating NAMs. Forums may include either EPA or NAS-led meetings/workshops. EPA and NAS-led meetings and/or workshops shall address key science topics including, but not limited to new assessment methods (NAM); in vitro assay development and model systems toxicology; human health risk assessment; biostatistics; veterinary medicine and other scientific issues identified relevant for peer-review of draft assessment documents. The final product shall include data tables resulting from literature reviews as well as narrative comments pertaining to each section outlined below. The components of the review consist of the following:

**1. Variability and Human Relevance of Existing Laboratory Mammalian Toxicity Tests:**

- Review the scientific literature pertaining to the qualitative and quantitative variability in laboratory mammalian toxicity tests.
- Review the scientific literature on the overall concordance between laboratory mammalian models and humans in the adverse effects following exposure to commercial, environmental, and pharmaceutical chemicals, where available.

**2. Frameworks for Validation and Establishing Scientific Confidence:**

- Review the scientific literature on validation of laboratory mammalian toxicity tests.
- Review frameworks for establishing scientific confidence in NAMs.
- Identify and describe the issues in the validation of NAMs as a replacement for existing laboratory mammalian toxicity tests.
- Identify and describe the issues in the validation of NAMs that use cells or proteins of human origin in comparison to laboratory mammalian toxicity data.
- Identify and describe the issues in the validation of NAMs that are not intended as one-to-one replacements for laboratory mammalian toxicity studies.

**3. Identification of Research Needs:**

- Determine information gaps in the areas listed above to identify research priorities that could better inform these recommendations.

**D. CHARGE QUESTIONS TO THE EXPERT COMMITTEE**

Specifically, the Committee shall answer and provide feedback on the following:

1. Does the Committee believe the literature review and data provided reflect a comprehensive, workable, objective, and transparent process?

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2. Given the results of the literature review and workshops, what are the implications of the qualitative and quantitative variability of laboratory mammalian toxicity studies when using them to establish the performance of NAMs?
3. Given the results of the literature review and workshops, what is the concordance between laboratory mammalian models and humans in the adverse effects following chemical exposure and how might this frame expectations of NAMs when they cannot be compared directly with human studies?
4. The Committee shall impart expert advice on addressing the two related issues that were left unresolved in the 2017 NRC report:
  - a. Evaluation of the validity of assays that are not intended as one-to-one replacements for in vivo toxicity assays; and
  - b. Assessment of the concordance of data from assays that use cells or proteins of human origin with toxicity data that are virtually all derived from animal models.
5. Based on the conclusions from 1 – 4 above, how may the Committee foresee this information being incorporated into a new or the existing validation paradigm or scientific confidence framework so that EPA can ensure that NAMs are equivalent to or better than the animal tests replaced?

## **E. DESCRIPTION OF TASKS**

NAS' identified subject matter experts and committee members shall convene to complete the activities defined in this Performance Work Statement. The tasks are the following:

### **Task 1 – Establish Public Workshops (Contract level PWS Task Area 2)**

The NAS shall establish two (2) public workshops. The first workshop shall focus on strengths and limitations with using laboratory animal toxicology data as the benchmark for developing and evaluating NAMs. The intent of the first workshop is to ensure a more consistent understanding of the issues and current scientific knowledge across the scientific and stakeholder communities. In addition, the scope of the literature will be presented for input from the scientific and stakeholder communities. The second workshop shall discuss the charge questions to the committee and provide input to the committee in support of the literature review. The NAS shall convene and facilitate the committee either via webinar or in-person if appropriate for deliberation following the public workshop and as needed to complete the final report. NAS shall

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provide recognized national and international experts an opportunity to discuss critical science topics relevant to scientific priorities.

***Subtask 1.1 – Initial meeting:*** Convene a meeting with the EPA and NAS to review the topics and issues to be discussed at the workshop(s). EPA will identify the topics and review issues via email anticipated to be discussed for each workshop approximately six (6) months before the workshop. If necessary, EPA will provide a one-pager with the necessary background information. This preliminary meeting shall occur within seven (7) days of EPA identifying the topics and anticipated issues.

***Subtask 1.2 – Establish a workshop agenda and a list of participants:*** NAS shall convene up to 15 experts to participate in the workshop. NAS shall identify and contact non-federal and federal subject matter experts who are (a) recognized experts in the field(s) and issues relevant to the workshop, (b) represent a range of recognized views on the issues identified by EPA, and (c) are available to present and discuss their research and individual views at the public workshop. Experts with an understanding of regulatory risk assessment (e.g., chemical hazards) are generally preferred. NAS shall provide the EPA TOCOR a proposed list of experts including a biographical sketch, proposed area of expertise for each expert, and if there are any issues regarding potential COI or impartiality. NAS shall convene a meeting with the EPA TOCOR and ORD management and technical staff to review the proposed list of experts. EPA may provide comments on the proposed list regarding qualifications and COI/impartiality. NAS shall determine who will participate in the workshop.

***Subtask 1.3. – Conduct the workshop(s):*** NAS shall convene and facilitate up to two (2) workshops to discuss topics and/or issues pertinent to assessment development. In coordination with the NAS, EPA will provide a general description of the desired goals and outcomes of each workshop. NAS shall provide EPA with a list of all registrants and participants after the workshop/meeting via email.

***Subtask 1.4. – Make arrangements for transportation, lodging and logistical support for each expert asked to participate in the workshop(s).***

NAS shall arrange provision for transportation, lodging, and any other logistical support for the experts' participation in the workshop(s)/meeting(s).

***Subtask 1.5 – Develop Workshop Outputs***

NAS shall develop one (1) rapporteur report for each workshop.

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**Task 1 Deliverables**

- a) For the workshops requested, the TOCOR shall be informed via email of the time, location, and agenda of the meeting at least 45 days prior to the meeting. All communications regarding public meetings should go through the TOCOR. The NAS shall provide EPA with a final list of all workshop attendees and public commenters within five (5) business days of the meeting (Subtask 1.2).
- b) Arrangement and provision of transportation, lodging, and any other logistical support for the experts' participation in the workshops (Subtask 1.4).
- c) If public websites or similar means are used to disseminate information to the public during the course of this task, the TOCOR shall be notified of the location of such information (e.g., websites), as well as relevant changes to them (Task 1).
- d) Identified workshop report (Subtask 1.5).

**Task 2 – Convene Expert Committee (Contract level PWS Task Area 2)**

Based on the results of the first workshop NAS shall identify and convene a proposed group of subject matter experts to serve on the committee, not to exceed fifteen (15) who are recognized experts in one or more of the fields relevant to the workshop including: in vitro assay development and model systems toxicology; human health risk assessment; biostatistics; and veterinary medicine. The EPA may offer suggestions of potential committee members to be considered by the NAS during its nominations process. EPA may also comment on the proposed committee membership during the 20-day comment period. The NAS will select the committee members.

***Subtask 2.1: Perform literature review***

The NAS shall use a systematic approach to provide a review of published literature pertaining to the variability and human relevance of current laboratory mammalian toxicity tests and approaches to validation and establishing scientific confidence in using NAMs. The variability and relevance of the existing laboratory mammalian toxicity tests shall be considered by the NAS in terms of reliability, qualitative and quantitative reproducibility as well as biological relevance and overall concordance of the results in humans.

***Subtask 2.2: Recruit Experts:*** NAS shall identify a proposed group of subject matter experts to serve on the committee, not to exceed fifteen (15) who are (a) recognized experts in the field(s) relevant to the request, (b) represent a range of broadly recognized views on the issues identified by EPA, (c) are available to present and discuss their

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individual views at the workshop, and (d) have been evaluated for conflict of interest or lack of impartiality.

**Subtask 2.3 – Post-Recruitment Meeting:** Provide the TOCOR a proposed list of SMEs including a biographical sketch, proposed area of expertise for each SME, and if there are any issues regarding potential conflict of interest (COI) or impartiality. Convene a meeting with the EPA and NAS to review the proposed list of SMEs.

EPA will provide comments on the proposed list regarding qualifications and COI/impartiality. NAS shall determine who will participate in each workshop. NAS shall then deliver a final list of participants.

**Subtask 2.4 – Expert Logistic Support:** NAS shall coordinate workshop logistics information (e.g., webinar and teleconference information) between EPA and the SMEs. Generally, these workshops are expected to be conducted via webinar but if necessary, NAS shall make arrangements for transportation, lodging and logistical support for each SMEs asked to participate in the workshop to be held in Washington, D.C.-or another location as specified by EPA-for up to two (2) workshops.

**Subtask 2.5 – Comment Compilation:** NAS shall compile non-consensus input from each SME on topics discussed at the workshop for delivery to the TOCOR.

## **Task 2 Deliverables**

- a) The primary products for each workshop are expected to be: (a) proposed and final lists of experts including biographical sketches, which will participate in each of the two (2) workshops specified by EPA, (b) review of potential COI and partiality issues for each expert and report of any potential issue to the TOCOR, and (c) develop a document of compiled comments from each expert to provide to EPA that may be published externally (Task 2).
- b) Participation of the experts in NAS workshops. Arrangement and provision of transportation, lodging, and any other logistical support for the experts' participation in the workshops (Task 2).

## **Task 3 – Write Report**

The NAS shall write a report presenting the NAS committee's findings regarding the charge questions and the results of both workshops and the process followed by the committee to develop those findings and recommendations shall be delivered prior to expiration of this task order.

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***Subtask 3.1: Conduct an independent peer review***

NAS shall conduct an independent peer review for a final report. In coordination with NAS, EPA will transmit the external peer review assessment materials, prior to the peer review. EPA also requests that NAS organize an external peer review meeting(s) for the peer review committee to discuss the draft assessment with EPA and to include an opportunity for public comment.

***Subtask 3.2: Deliver Final Report***

NAS shall deliver a final report presenting the NAS Committees findings regarding the charge questions and the results of both workshops.

**Task 3 Deliverables**

- a) If public websites or similar means are used to disseminate information to the public during the course of this task, the TOCOR shall be notified of the location of such information (e.g., websites), as well as relevant changes to them (Task 3).
- b) Peer reviewed final report detailing the NAS committee's findings regarding the charge questions to the committee. (Subtask 3.2)

**Task 4 – Monthly Progress Reports to TOCOR**

The contractor shall write and submit monthly progress reports to the TOCOR. Progress reports shall describe completed work during the invoice period and should link to charges described in invoice documentation.

***Subtask 4.1: Deliver Monthly Progress Reports to TOCOR***

Monthly progress reports shall include a written monthly technical progress report that includes the following: (a) an overview of work accomplished since project inception; (b) a description of work accomplished during the reporting period; (c) a summary of QA/QC activities since project inception including a summary of corrective action taken; (d) a brief summary of anticipated work during the following period; (e) a summary and details of the costs incurred for each task during the quarter and cumulatively; and (f) total remaining budget. Routine progress reports shall be delivered electronically; paper copies are not required.

**Task 4 Deliverables**

- a) EPA requests that written progress reports be provided to TOCOR monthly including an update of the project milestones. (Subtask 4.1)

**F. COVID Considerations**

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If appropriate, the NAS may conduct the workshops as face-to-face meetings. Options for face-to-face and virtual meetings may be included in the proposal.

**G. ACCEPTANCE CRITERIA**

The Contractor shall prepare high quality products and that are reproducible and transparent. Figures submitted shall be of high quality similar to presentations developed for national scientific forums to be formatted as jpeg or TIFF files. Deliverables shall be edited for grammar, spelling, and logic flow as well as, technical accuracy, completeness, timeliness, grammatically correct, free of typographical errors, and conformance with the specific task, charge and expertise and deliverables of this Performance Work Statement. The technical information shall be reasonable complete and presented in a logical, readable manner. Text deliverables shall be provided in Microsoft Word 2016 and *Adobe Acrobat*, or compatible formats. Deliverables will be accepted upon review and approval by the TOCOR.

**H. EPA Technical Experts:** Russell Thomas and Maureen Gwinn



<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>				1. CONTRACT ID CODE		PAGE 1 OF 2 PAGES	
2. AMENDMENT/MODIFICATION NO. P00001		3. EFFECTIVE DATE See Block 16C		4. REQUISITION/PURCHASE REQ. NO.		5. PROJECT NO. (If applicable)	
6. ISSUED BY CAD		CODE CAD		7. ADMINISTERED BY (If other than Item 6)		CODE	
US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001							
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)  National Academy of Sciences Attn: JAMES BURKE 500 FIFTH STREET NW WASHINGTON DC 200012736				(x)			
				9A. AMENDMENT OF SOLICITATION NO.			
				9B. DATED (SEE ITEM 11)			
				x 10A. MODIFICATION OF CONTRACT/ORDER NO. 68HERC19D0011 68HERC21F0178			
				10B. DATED (SEE ITEM 13) 03/23/2021			
CODE 041964057		FACILITY CODE					

<b>CONTINUATION SHEET</b>	REFERENCE NO. OF DOCUMENT BEING CONTINUED 68HERC19D0011/68HERC21F0178/P00001	PAGE	OF
		2	2

NAME OF OFFEROR OR CONTRACTOR  
National Academy of Sciences

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Payment: RTP Finance Center US Environmental Protection Agency RTP-Finance Center (AA216-01) 109 TW Alexander Drive www2.epa.gov/financial/contracts Durham NC 27711 Period of Performance: 03/23/2021 to 03/21/2023				

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>		1. CONTRACT ID CODE		PAGE OF PAGES 1 2	
2. AMENDMENT/MODIFICATION NO. P00002		3. EFFECTIVE DATE See Block 16C		4. REQUISITION/PURCHASE REQ. NO.	
5. PROJECT NO. (If applicable)		6. ISSUED BY CAD		7. ADMINISTERED BY (If other than Item 6) CODE	
CAD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001		8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) National Academy of Sciences Attn: JAMES BURKE 500 FIFTH STREET NW WASHINGTON DC 200012736		9A. AMENDMENT OF SOLICITATION NO. 9B. DATED (SEE ITEM 11)	
CODE 041964057		FACILITY CODE		10A. MODIFICATION OF CONTRACT/ORDER NO. 68HERC19D0011 68HERC21F0178 10B. DATED (SEE ITEM 13) 03/23/2021	

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.  
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning \_\_\_\_\_ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)  
See Schedule

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

**E. IMPORTANT:** Contractor ☒ is not ☐ is required to sign this document and return \_\_\_\_\_ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)  
DUNS Number: 041964057  
TOCOR: KAI THOMPSON Max Expire Date: 03/22/2023  
LIST OF CHANGES:  
Reason for Modification: The purpose of this modification will be to execute the revised PWS for this no cost change.

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) William M. Yates	
15B. CONTRACTOR/OFFEROR  (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA  ELECTRONIC SIGNATURE (Signature of Contracting Officer)	16C. DATE SIGNED 09/28/2021

Previous edition unusable

<b>CONTINUATION SHEET</b>	REFERENCE NO. OF DOCUMENT BEING CONTINUED 68HERC19D0011/68HERC21F0178/P00002	PAGE	OF
		2	2

NAME OF OFFEROR OR CONTRACTOR  
National Academy of Sciences

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Payment: RTP Finance Center US Environmental Protection Agency RTP-Finance Center (AA216-01) 109 TW Alexander Drive www2.epa.gov/financial/contracts Durham NC 27711 Period of Performance: 03/23/2021 to 03/21/2023				

Performance Work Statement  
National Academy of Sciences (NAS)  
Contract #68HERC19D0011  
PR-ORD-21-00431  
PR-OCSP-21-00045  
Task Order: #68HERC21F0178

**I. TITLE:** Variability and Relevance of Current Laboratory Mammalian Toxicity Tests and Expectations for New Approach Methods (NAMs) for use in Human Health Risk Assessment

**II. Task Order Contracting Officer Representative(s):**

<b>Task Order Contracting Officer Representative (TOCOR)</b> Name: Kai Thompson <b>Office:</b> CCTE/IO U.S EPA 109 T.W. Alexander Drive Mail Code: D149-02 RTP, NC 27711  Telephone: 919-541-5243 E-mail: thompson.kai@epa.gov	<b>Alternate Task Order Contracting Officer Representative (Alt. TOCOR)</b> Name: Alexander Hanf Office: CCTE/CRPIS U.S EPA 109 T.W. Alexander Drive Mail Code: D143-02 RTP, NC 27711  Telephone: 919-541-2750 E-mail: hanf.alexander@epa.gov
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**III. PERIOD OF PERFORMANCE:** Date of Task Order award through 24 months following award

**A. PURPOSE OF TASK ORDER**

The National Academy of Sciences (NAS) shall provide the Environmental Protection Agency (EPA) with a review of the variability and relevance of existing laboratory mammalian toxicity tests for human health risk assessment to inform the development of approaches for validation and establishing scientific confidence in using New Approach Methods (NAMs), and recommendations on expectations associated with NAMs when they cannot be compared with human studies, by hosting two (2) workshops and establishing an expert committee, described in the Scope of Work and Tasks 1-4 below.

**B. BACKGROUND**

In 2017, National Research Council (NRC) released a report entitled “Using 21st Century Science to Improve Risk-Related Evaluations.” The risk-related applications report highlighted both the progress that had occurred in toxicology and exposure sciences since the release of previous

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reports and identified several decision contexts that could benefit from application of the advances in the fields. It proposed a shift in thinking of the risk assessment community from whether a chemical causes a particular effect to whether a chemical increases the risk of a particular effect, while also recognizing that one does not need to know all the pathways or components involved in a particular disease to begin applying the new tools to regulatory decisions. The NRC Committee on Incorporating 21st Century Science into Risk-Based Evaluations also touched on the subject of validation and that many of the traditional processes for validation cannot match the pace of development of new assays, models, and test systems. The report recognized the challenges in validating a NAM where there is no “gold standard” or against toxicity tests that have not themselves been validated. The NRC Committee highlighted that there were two important issues on which there was still no consensus in the scientific community: 1) evaluation of the validity of assays that are not intended as one-to-one replacements for *in vivo* toxicity assays; and 2) assessment of the concordance of data from assays that use cells or proteins of human origin with toxicity data that are virtually all derived from animal models.

One of the important considerations in the evaluation of ‘equivalent or better’ approaches is that laboratory mammalian toxicity data provide a part of the foundation of the current risk assessment paradigm, and mammalian studies often provide the only available *in vivo* data for many environmental chemicals. There are a number of new evaluations of the qualitative and quantitative variability (Kleinstreuer *et al.*, 2016; Browne *et al.*, 2018; Pham *et al.*, 2020) and human relevance (e.g., Monticello *et al.*, 2017; Hoffmann *et al.*, 2018; Ackley *et al.*, 2019), of laboratory mammalian toxicity studies. These new studies highlight some of the limitations and challenges associated with using laboratory mammalian toxicity data as the standard benchmark for evaluating and implementing NAMs. Since the 2017 NRC report on 21<sup>st</sup> Century risk-related evaluations, the state of the science has continued to progress and the understanding and experience with NAMs has led to new considerations and more focused scientific questions. EPA is soliciting support from NAS to explore the strengths and limitations of using laboratory mammalian toxicology data as the benchmark for developing and evaluating NAMs, as well as possible novel approaches to validation and confidence building in using NAMs to replace mammalian toxicology data. This scientific exploration will become important in the policy decisions that EPA needs to address with “validation to ensure that NAMs are equivalent to or better than the animal tests replaced.”

### C. SCOPE OF WORK

Performance Work Statement  
National Academy of Sciences (NAS)  
Contract #68HERC19D0011  
PR-ORD-21-00431  
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The NAS shall provide the EPA with a mechanism to recruit NAS identified subject-matter experts and when necessary, provide a forum for discussion(s) on science topics pertinent to using laboratory animal toxicology data as the benchmark for developing and evaluating NAMs. Forums may include either EPA or NAS-led meetings/workshops. EPA and NAS-led meetings and/or workshops shall address key science topics including, but not limited to new assessment methods (NAM); in vitro assay development and model systems toxicology; human health risk assessment; biostatistics; veterinary medicine and other scientific issues identified relevant for peer-review of draft assessment documents. The final product shall include data tables resulting from literature reviews as well as narrative comments pertaining to each section outlined below. The components of the review consist of the following:

**1. Variability and Human Relevance of Existing Laboratory Mammalian Toxicity Tests:**

- Review the scientific literature pertaining to the qualitative and quantitative variability in laboratory mammalian toxicity tests.
- Review the scientific literature on the overall concordance between laboratory mammalian models and humans in the adverse effects following exposure to commercial, environmental, and pharmaceutical chemicals, where available.

**2. Frameworks for Validation and Establishing Scientific Confidence:**

- Review the scientific literature on validation of laboratory mammalian toxicity tests.
- Review frameworks for establishing scientific confidence in NAMs.
- Identify and describe the issues in the validation of NAMs as a replacement for existing laboratory mammalian toxicity tests.
- Identify and describe the issues in the validation of NAMs that use cells or proteins of human origin in comparison to laboratory mammalian toxicity data.
- Identify and describe the issues in the validation of NAMs that are not intended as one-to-one replacements for laboratory mammalian toxicity studies.

**3. Identification of Research Needs:**

- Determine information gaps in the areas listed above to identify research priorities that could better inform these recommendations.

**D. CHARGE QUESTIONS TO THE EXPERT COMMITTEE**

Specifically, the Committee shall answer and provide feedback on the following:

1. Does the Committee believe the literature review and data provided reflect a comprehensive, workable, objective, and transparent process?

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National Academy of Sciences (NAS)  
Contract #68HERC19D0011  
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2. Given the results of the literature review and workshops, what are the implications of the qualitative and quantitative variability of laboratory mammalian toxicity studies when using them to establish the performance of NAMs?
3. Given the results of the literature review and workshops, what is the concordance between laboratory mammalian models and humans in the adverse effects following chemical exposure and how might this frame expectations of NAMs when they cannot be compared directly with human studies?
4. The Committee shall impart expert advice on addressing the two related issues that were left unresolved in the 2017 NRC report:
  - a. Evaluation of the validity of assays that are not intended as one-to-one replacements for in vivo toxicity assays; and
  - b. Assessment of the concordance of data from assays that use cells or proteins of human origin with toxicity data that are virtually all derived from animal models.
5. Based on the conclusions from 1 – 4 above, how may the Committee foresee this information being incorporated into a new or the existing validation paradigm or scientific confidence framework so that EPA can ensure that NAMs are equivalent to or better than the animal tests replaced?

## **E. DESCRIPTION OF TASKS**

NAS' identified subject matter experts and committee members shall convene to complete the activities defined in this Performance Work Statement. The tasks are the following:

### **Task 1 – Establish Public Workshops (Contract level PWS Task Area 2)**

The NAS shall establish two (2) public workshops. The first workshop shall focus on strengths and limitations with using laboratory animal toxicology data as the benchmark for developing and evaluating NAMs. The intent of the first workshop is to ensure a more consistent understanding of the issues and current scientific knowledge across the scientific and stakeholder communities. The second workshop shall provide input to the committee in support of the consensus report development. The NAS shall convene and facilitate the committee either via webinar or in-person if appropriate for deliberation following the public workshop and as needed to complete the final report. NAS shall provide recognized national and international experts an opportunity to discuss critical science topics relevant to scientific priorities.



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***Subtask 1.1 – Initial meeting:*** Convene a meeting with the EPA and NAS to review the topics and issues to be discussed at the workshop(s). EPA will identify the topics and review issues via email anticipated to be discussed for each workshop approximately three to six (3-6) months before the workshop. If necessary, EPA will provide a one-pager with the necessary background information. This preliminary meeting shall occur within seven (7) days of EPA identifying the topics and anticipated issues.

***Subtask 1.2 – Establish a workshop agenda and a list of participants:*** NAS shall convene up to 15 experts to participate in the workshop. NAS shall identify and contact non-federal and federal subject matter experts who are (a) recognized experts in the field(s) and issues relevant to the workshop, (b) represent a range of recognized views on the issues identified by EPA, and (c) are available to present and discuss their research and individual views at the public workshop. Experts with an understanding of regulatory risk assessment (e.g., chemical hazards) are generally preferred. NAS shall provide the EPA TOCOR a proposed list of experts including a biographical sketch, proposed area of expertise for each expert, and if there are any issues regarding potential COI or impartiality. NAS shall convene a meeting with the EPA TOCOR and ORD management and technical staff to review the proposed list of experts. EPA may provide comments on the proposed list regarding qualifications and COI/impartiality. NAS shall determine who will participate in the workshop.

***Subtask 1.3. – Conduct the workshop(s):*** NAS shall convene and facilitate up to two (2) workshops to discuss topics and/or issues pertinent to assessment development. In coordination with the NAS, EPA will provide a general description of the desired goals and outcomes of each workshop. NAS shall provide EPA with a list of all registrants and participants after the workshop/meeting via email.

***Subtask 1.4. – Make arrangements for transportation, lodging and logistical support for each expert asked to participate in the workshop(s).***

NAS shall arrange provision for transportation, lodging, and any other logistical support for the experts' participation in the workshop(s)/meeting(s).

**Subtask 1.5 – Develop Workshop Outputs**

NAS shall develop one (1) rapporteur report for each workshop.

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**Task 1 Deliverables**

- a) For the workshops requested, the TOCOR shall be informed via email of the time, location, and agenda of the meeting at least 45 days prior to the meeting. All communications regarding public meetings should go through the TOCOR. The NAS shall provide EPA with a final list of all workshop attendees and public commenters within five (5) business days of the meeting (Subtask 1.2).
- b) Arrangement and provision of transportation, lodging, and any other logistical support for the experts' participation in the workshops (Subtask 1.4).
- c) If public websites or similar means are used to disseminate information to the public during the course of this task, the TOCOR shall be notified of the location of such information (e.g., websites), as well as relevant changes to them (Task 1).
- d) Identified workshop report (Subtask 1.5).

**Task 2 – Convene Expert Committee (Contract level PWS Task Area 2)**

NAS shall identify and convene a proposed group of subject matter experts to serve on the committee, not to exceed sixteen (16) who are recognized experts in one or more of the fields relevant to the workshop including: in vitro assay development and model systems toxicology; human health risk assessment; biostatistics; and veterinary medicine. The EPA may offer suggestions of potential committee members to be considered by the NAS during its nominations process. EPA may also comment on the proposed committee membership during the 20-day comment period. The NAS will select the committee members.

***Subtask 2.1: Perform literature review***

The NAS shall use a systematic approach to provide a review of published literature pertaining to the variability and human relevance of current laboratory mammalian toxicity tests and approaches to validation and establishing scientific confidence in using NAMs. The variability and relevance of the existing laboratory mammalian toxicity tests shall be considered by the NAS in terms of reliability, qualitative and quantitative reproducibility as well as biological relevance and overall concordance of the results in humans.

***Subtask 2.2: Recruit Experts:*** NAS shall identify a proposed group of subject matter experts to serve on the committee, not to exceed sixteen (16) who are (a) recognized experts in the field(s) relevant to the request, (b) represent a range of broadly recognized views on the issues identified by EPA, (c) are available to present and discuss their

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individual views at the workshop, and (d) have been evaluated for conflict of interest or lack of impartiality.

**Subtask 2.3 – Post-Recruitment Notification:** Provide the TOCOR a proposed list of SMEs including a biographical sketch and proposed area of expertise for each SME. NAS will evaluate any issues regarding potential conflict of interest (COI) or impartiality.

EPA may provide comments on the provisional committee appointments during the 20-day public comment period. NAS shall determine who will participate in each workshop. NAS shall then deliver a final list of participants.

**Subtask 2.4 – Expert Logistic Support:** NAS shall coordinate workshop logistics information (e.g., webinar and teleconference information) between EPA and the SMEs. Generally, these workshops are expected to be conducted via webinar but if necessary, NAS shall make arrangements for transportation, lodging and logistical support for each SMEs asked to participate in the workshop to be held in Washington, D.C.-or another location as specified by EPA-for up to two (2) workshops.

**Subtask 2.5 – Comment Compilation:** NAS shall compile non-consensus input from each SME on topics discussed at the workshop for delivery to the TOCOR.

## Task 2 Deliverables

- a) The primary products for each workshop are expected to be: (a) proposed and final lists of experts including biographical sketches, which will participate in each of the two (2) workshops specified by EPA, and (b) develop a document of compiled comments from each expert to provide to EPA that may be published externally (Task 2).
- b) Participation of the experts in NAS workshops. Arrangement and provision of transportation, lodging, and any other logistical support for the experts' participation in the workshops (Task 2).

## Task 3 – Write Report

The NAS shall write a report presenting the NAS committee's findings regarding the charge questions and the results of both workshops and the process followed by the committee to develop those findings and recommendations shall be delivered prior to expiration of this task order.

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***Subtask 3.1: Conduct an independent peer review***

NAS shall conduct an independent peer review for a final report. In coordination with NAS, EPA will transmit the external peer review assessment materials, prior to the peer review. EPA also requests that NAS organize an external peer review meeting(s) for the peer review committee to discuss the draft assessment with EPA and to include an opportunity for public comment.

***Subtask 3.2: Deliver Final Report***

NAS shall deliver a final report presenting the NAS Committees findings regarding the charge questions and the results of both workshops.

**Task 3 Deliverables**

- a) If public websites or similar means are used to disseminate information to the public during the course of this task, the TOCOR shall be notified of the location of such information (e.g., websites), as well as relevant changes to them (Task 3).
- b) Peer reviewed final report detailing the NAS committee's findings regarding the charge questions to the committee. (Subtask 3.2)

**Task 4 – Monthly Progress Reports to TOCOR**

The contractor shall write and submit monthly progress reports to the TOCOR. Progress reports shall describe completed work during the invoice period and should link to charges described in invoice documentation.

***Subtask 4.1: Deliver Monthly Progress Reports to TOCOR***

Monthly progress reports shall include a written monthly technical progress report that includes the following: (a) an overview of work accomplished since project inception; (b) a description of work accomplished during the reporting period; (c) a summary of QA/QC activities since project inception including a summary of corrective action taken; (d) a brief summary of anticipated work during the following period; (e) a summary and details of the costs incurred for each task during the quarter and cumulatively; and (f) total remaining budget. Routine progress reports shall be delivered electronically; paper copies are not required.

**Task 4 Deliverables**

- a) EPA requests that written progress reports be provided to TOCOR monthly including an update of the project milestones. (Subtask 4.1)

**F. COVID Considerations**

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National Academy of Sciences (NAS)  
Contract #68HERC19D0011  
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If appropriate, the NAS may conduct the workshops as face-to-face meetings. Options for face-to-face and virtual meetings may be included in the proposal.

**G. ACCEPTANCE CRITERIA**

The Contractor shall prepare high quality products and that are reproducible and transparent. Figures submitted shall be of high quality similar to presentations developed for national scientific forums to be formatted as jpeg or TIFF files. Deliverables shall be edited for grammar, spelling, and logic flow as well as, technical accuracy, completeness, timeliness, grammatically correct, free of typographical errors, and conformance with the specific task, charge and expertise and deliverables of this Performance Work Statement. The technical information shall be reasonable complete and presented in a logical, readable manner. Text deliverables shall be provided in Microsoft Word 2016 and *Adobe Acrobat*, or compatible formats. Deliverables will be accepted upon review and approval by the TOCOR.

**H. EPA Technical Experts:** Russell Thomas and Nisha Sipes

# ORDER FOR SUPPLIES OR SERVICES

PAGE OF PAGES

1

2

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER 04/07/2021		2. CONTRACT NO. (If any) 68HERC19D0011		6. SHIP TO: a. NAME OF CONSIGNEE OAR/ORIA	
3. ORDER NO. 68HERC21F0203		4. REQUISITION/REFERENCE NO. PR-OAR-21-00542			
5. ISSUING OFFICE (Address correspondence to) CAD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001				b. STREET ADDRESS US Environmental Protection Agency Mail Code 6601J 1200 Pennsylvania Avenue NW	
				c. CITY Washington	e. ZIP CODE 20460
7. TO: JAMES BURKE				f. SHIP VIA	
a. NAME OF CONTRACTOR National Academy of Sciences					
b. COMPANY NAME				8. TYPE OF ORDER	
c. STREET ADDRESS 500 FIFTH STREET NW				<input type="checkbox"/> a. PURCHASE REFERENCE YOUR:  Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.	
d. CITY WASHINGTON				e. STATE DC	f. ZIP CODE 200012736
9. ACCOUNTING AND APPROPRIATION DATA See Schedule				10. REQUISITIONING OFFICE Office of Research and Development	
11. BUSINESS CLASSIFICATION (Check appropriate box(es))					
<input type="checkbox"/> a. SMALL <input checked="" type="checkbox"/> b. OTHER THAN SMALL <input type="checkbox"/> c. DISADVANTAGED <input type="checkbox"/> d. WOMEN-OWNED <input type="checkbox"/> e. HUBZone <input type="checkbox"/> f. SERVICE-DISABLED VETERAN-OWNED <input type="checkbox"/> g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM <input type="checkbox"/> h. EDWOSB					
12. F.O.B. POINT					
13. PLACE OF		14. GOVERNMENT B/L NO.		15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 04/06/2023	
a. INSPECTION Destination	b. ACCEPTANCE Destination			16. DISCOUNT TERMS	

## 17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	DUNS Number: 041964057 TOCOR: ALISON CLUNE  Continued ...					

SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT		19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		17(h) TOTAL (Cont. pages)
	21. MAIL INVOICE TO:						
	a. NAME RTP Finance Center						\$404,962.00
	b. STREET ADDRESS (or P.O. Box) US Environmental Protection Agency RTP-Finance Center (AA216-01) 109 TW Alexander Drive www2.epa.gov/financial/contracts						\$404,962.00
c. CITY Durham			d. STATE NC	e. ZIP CODE 27711		17(i) GRAND TOTAL	

22. UNITED STATES OF

AMERICA BY (Signature)

04/07/2021

ELECTRONIC  
SIGNATURE

23. NAME (Typed)

William M. Yates

TITLE: CONTRACTING/ORDERING OFFICER

**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

PAGE NO  
2

**IMPORTANT:** Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 04/07/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0203
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
0001	Admin Office: CAD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001 Accounting Info: 21-22-B-33B00BL-000AH5-2505-2133BEE008-001 BFY: 21 EFY: 22 Fund: B Budget Org: 33B00BL Program (PRC): 000AH5 Budget (BOC): 2505 DCN - Line ID: 2133BEE008-001 Period of Performance: 04/07/2021 to 04/06/2023  Amend to add the additional funding required (10005388 NAE) under Contract# 68HERC190011 in the amount of \$4,934.18 and to submit a revised PWS Consensus report on the health risks of indoor exposures to PM2.5 and practical mitigation solutions; Mark Cranley, Contract Officer; William Yates, Contract Specialist, TOCOR: Alison Clune; CL COR: Glennis Reslock				404,962.00	

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$404,962.00

## PERFORMANCE WORK STATEMENT

National Academy of Sciences (NAS)

Contract #68HERC190011

PR-OAR-21-00542

Task Order #68HERC21F0203

**I. TITLE:** Consensus report on the health risks of indoor exposures to PM<sub>2.5</sub> and practical mitigation solutions

**EAS Short Title:** Consensus report indoor particulate matter and practical solutions

### II. Task Order Contracting Officer Representative(s):

<b>Task Order Contracting Officer Representative (TOCOR)</b> <b>Name:</b> Alison Clune <b>Office:</b> OAR/ORIA/IED/CSA William Jefferson Clinton Building - West 1200 Pennsylvania Ave NW Mail Code 6909T; Room 1318G Washington, DC 20460  <b>Phone:</b> 202-343-9874 <b>Email:</b> clune.alison@epa.gov	<b>Alternate Task Order Contracting Officer Representative (Alt. TOCOR)</b> <b>Name:</b> Laura Kolb <b>Office:</b> OAR/ORIA/IED/CSA William Jefferson Clinton Building - West 1200 Pennsylvania Ave NW Mail Code 6909T; Room 1212A Washington, DC 20460  <b>Phone:</b> 202-343-9438 <b>Email:</b> kolb.laura@epa.gov
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**III. PERIOD OF PERFORMANCE:** Date of Task Order award through 24 months following award.

### IV. PURPOSE OF TASK ORDER

The purpose of this task order (TO) is to produce a consensus study report authored by a committee of scientific experts and leaders convened by the National Academy of Sciences, Engineering, and Medicine (NASEM) to synthesize the state-of-the-science on the health impacts of indoor fine particulate matter (PM<sub>2.5</sub>) and evaluate engineering solutions and interventions to reduce risks of exposure to PM<sub>2.5</sub> indoors.

### V. BACKGROUND

Particles dominate the health impact of air pollution and can originate from both indoor and outdoor sources. Particle pollution generated outdoors can infiltrate into indoor environments and add to particle levels from indoor activities such as cooking and cleaning. Because people



spend about 90% of their time indoors, most of the exposure to PM<sub>2.5</sub> from both indoor and outdoor sources takes place in indoor environments.

The mission of EPA's Office of Radiation and Indoor Air (ORIA) within the Office of Air and Radiation (OAR) is to protect the public and the environment from radiation and indoor air pollution. This consensus report will strongly support ORIA's efforts to build a solid scientific foundation on priority areas related to indoor air quality (IAQ) including indoor PM<sub>2.5</sub>. ORIA expects to use the report to communicate the importance of indoor exposure to PM<sub>2.5</sub> and develop new and revised guidance on engineering and behavioral solutions to reduce exposure. The consensus report will support ORIA's partnerships and outreach through states, tribes, local governments, non-governmental organizations, industry and communities seeking to provide scientifically credible messaging on indoor PM<sub>2.5</sub> and practical mitigation solutions.

In 2016, ORIA commissioned the NASEM to convene a workshop titled *Health Risks of Indoor Exposure to Particulate Matter* on the health risks of indoor exposures to PM<sub>2.5</sub>, risk management approaches and further research needs. The workshop summary is available for download at <https://www.nap.edu/catalog/23531/health-risks-of-indoor-exposure-to-particulate-matter-workshop-summary>. Experts at the workshop presented evidence that demonstrated that indoor exposure to PM<sub>2.5</sub> is a serious public health issue, and the resulting report summarized the proceedings. Since the workshop, EPA, the research community, and IAQ-related industries have made substantial progress in this area including revised EPA guidance on residential air cleaners and filters, analyses on the impact of indoor-generated PM<sub>2.5</sub>, and the wide adoption of sensor-based technology to detect PM<sub>2.5</sub>. This work will build on that effort. At this stage, a more targeted, independent and authoritative analysis from NASEM will provide the basis for credible communication of risk and known countermeasures, and support for academic and business innovation in mitigating risk.

## **VI. SCOPE OF WORK**

The NASEM shall convene a committee of scientific experts to consider the state-of the-science on the health impacts of exposure PM<sub>2.5</sub> indoors and engineering solutions and interventions to reduce risks of exposure to PM<sub>2.5</sub> indoors, including practical mitigation solutions to reduce exposure in residential settings. Specifically, the committee shall focus on:

- Synthesizing and summarizing recent scientific literature to assess the health impacts of indoor exposure to PM<sub>2.5</sub>; and
- Identification and analysis of practical intervention approaches for PM<sub>2.5</sub> indoors.

The committee's consideration of this information shall lead to a consensus study report with findings and recommendations regarding 1) key implications of the scientific research for public health, including potential near-term opportunities for incorporating what is known into public health practice, and 2) where additional research will be most critical to understanding indoor exposure to PM<sub>2.5</sub> and the effectiveness of interventions. As appropriate, opportunities for

advancing such research by addressing methodological or technological barriers or enhancing coordination or collaboration will be noted. The indoor environments considered in this report will be limited to non-industrial exposure within buildings.

## **VII. DESCRIPTION OF TASKS**

### **Task 1: Kick-off Call and Project Milestone Chart (Contract Level PWS Task Area 2)**

EPA is requesting NASEM to convene a teleconference and provide a Project Milestone Chart for this TO.

#### **SubTask 1.1 Kick-off Call**

The NASEM shall convene a teleconference with the TOCOR and relevant EPA staff to review the objectives, technical requirements, and schedule for the consensus study report on exposure to PM<sub>2.5</sub> indoors, health effects, and practical mitigation solutions. The teleconference shall occur within fifteen (15) business days of acceptance of this task order on a mutually agreeable date.

#### **SubTask 1.2 Project Milestone Chart**

EPA requests that a project milestone chart for the consensus study be provided to the Contracting Officer (CO), Contract Level Contracting Officer Representative (CL COR) and TOCOR within one (1) month of task initiation. This project milestone chart should detail the significant activities for each task/subtask, and expected progression of the deliverables.

#### **Task 1. Deliverables**

<b>Task</b>	<b>SubTask</b>	<b>Deliverable</b>	<b>Schedule</b>
1	1.1	TO Kick-off Teleconference Minutes	Within 15 business days of acceptance of this TO
1	1.2	Project milestone chart	Within 1 month of acceptance of this TO

### **Task 2: Quality Assurance Documentation (Admin)**

The NASEM must provide acceptable quality assurance and quality control documentation to EPA within one (1) month of award of this agreement. Acceptable documentation will be a Quality Management Plan (QMP) and Quality Assurance Project Plan (QAPP). Work may not start until the QMP and QAPP are approved by the TOCOR and ORIA Indoor Environments Division (IED) Quality Assurance Coordinator (QAC). The QMP will be written in accordance with *EPA Requirements for Quality Management Plans* (EPA QA/R-2) and the QAPP will be written in accordance with *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5). Guidance on the content and format of a QAPP, including requirements for secondary data QAPPs, will be provided by EPA. The TOCOR will provide the NASEM with the QAC contact's

information upon request for pre-submittal questions. The NASEM shall copy the TOCOR on any communication with the QAC contact.

**Task 2. Deliverable**

Task	SubTask	Deliverable	Schedule
2	NA	Quality Management Plan (QMP) and Quality Assurance Project Plan (QAPP)	Within 1 month of acceptance of this TO

**Task 3: Identification of Consensus Study Committee (Contract Level PWS Task Area 2)**

The NASEM shall identify a committee of 6-12 subject matter experts who (a) are recognized experts in the field(s) relevant to the request, (b) represent a range of broadly recognized views on PM<sub>2.5</sub> and health effects from both indoor and outdoor sources, and (c) have been evaluated for conflict of interest or lack of impartiality. NASEM shall solicit nominations from the sponsor and consider those with other nominations to finalize a list of candidates but shall independently determine who will serve on the study committee. The NASEM shall provide the TOCOR a final list of committee members that includes biographical sketches that indicate their proposed area of expertise and will indicate if there are any issues regarding potential conflict of interest (COI) or impartiality within three (3) months of acceptance of this TO. EPA may provide comments on the list regarding qualifications and COI/impartiality.

**Task 3. Deliverable**

Task	SubTask	Deliverable	Schedule
4	NA	Final list of committee members including biographical sketches and report of COI/impartiality review	Within 3 months of acceptance of this TO

**Task 4: Committee Webinars including the Public, and/or Meetings & Creation of Webpage (Contract Level PWS Task Area 2)**

EPA is requesting NASEM to conduct committee teleconferences and provide a NASEM Webpage for this TO.

**SubTask 4.1 Committee Webinars including the Public, and/or Meetings**

The NASEM shall conduct public webinars and/or in-person meetings (as appropriate considering advisories and restrictions on travel and large gatherings related to the COVID-19 pandemic) to gather information from relevant experts and other stakeholders that will inform their consensus report. NASEM shall identify expert speakers to participate in the webinars and/or meetings. NASEM shall set up and manage the webinars and provide any

technical support for experts' participation. The TOCOR and alternate TOCOR shall be notified via email of the date, time, and agenda of the webinars and/or meetings at least one (1) month prior to the events. All communications regarding public teleconferences and/or meetings should go through the TOCOR and alternate TOCOR.

#### **SubTask 4.2 Creation of Webpage to Disseminate Study Information**

The NASEM shall create a NASEM webpage for dissemination of information about the study within six (6) months of acceptance of this TO. The TOCOR and alternate TOCOR shall be notified via email of the location of public websites or similar means used to disseminate information to the public during the course of this task, as well as relevant changes to them.

#### **SubTask 4.3 Recordings of Public Webinars and/or Meetings**

Public teleconferences and/or meetings (or public portions thereof) shall be recorded and made available on the NASEM website. The TOCOR and alternate TOCOR shall be notified via email of the location of public websites or similar means used to disseminate information to the public during the course of this task, as well as relevant changes to them.

#### **Task 4. Deliverables**

<b>Task</b>	<b>SubTask</b>	<b>Deliverable</b>	<b>Schedule</b>
4	4.1	Date, time, and agenda of public teleconferences	1 month prior to start of teleconference
4	4.2	NASEM webpage for dissemination of study information	Within 6 months of acceptance of this TO
4	4.3	Recordings of public webinars available on the NASEM website	Prior to release of consensus report (see Task 5)

#### **Task 5: Consensus Study Report on Indoor PM<sub>2.5</sub> Exposure and Practical Mitigation Solutions (Contract Level PWS Task Area 2)**

EPA is requesting that NASEM produce a consensus study report on the state-of-the-science on indoor PM<sub>2.5</sub> exposure and practical mitigation solutions.

#### **SubTask 5.1 Drafting and Peer-Review of Consensus Study Report**

The committee shall produce a draft consensus study report documenting the state-of-the-science on indoor PM<sub>2.5</sub> exposure and practical mitigation solutions, consistent with the scope of work/study charge as described in section VI. The state of the knowledge of the impacts of exposure to PM<sub>2.5</sub> in indoor environments and human health impacts will be addressed comprehensively and will include public health intervention strategies. Before release, the report shall be peer-reviewed by an external group of 10-12 experts to ensure that it addresses the scope of work/study charge and remains impartial and objective.

**SubTask 5.2 Pre-publication Consensus Study Report on NASEM Website**

Once finalized and approved by the NASEM, the report shall be released as a pre-publication Adobe PDF download to the public via the NASEM website. The TOCOR and alternate TOCOR shall be notified via email of the location of public websites or similar means used to disseminate information to the public during the course of this task, as well as relevant changes to them.

**SubTask 5.3 Final Consensus Study Report on NASEM Website and in Print**

Within 3 months of the pre-publication release, a final edited and bound version of the report shall be available in print and Adobe PDF download via the NASEM website. The TOCOR and alternate TOCOR shall be notified via email of the location of public websites or similar means used to disseminate information to the public during the course of this task, as well as relevant changes to them.

**SubTask 5.4 Printed Copies of Final Consensus Study Report**

The NASEM shall deliver 30 printed and professionally bound paperback copies of the final consensus study report (see SubTask 5.3) to the TOCOR.

**Task 5. Deliverables**

Task	SubTask	Deliverable	Schedule
5	5.1	Conduct peer-review of consensus study report	At least 6 months prior to expiration of this TO
5	5.2	Prepublication consensus study report available on NASEM website in Adobe PDF	At least 5 months prior to expiration of this TO
5	5.3	Final consensus study report available on NASEM website in Adobe PDF and in print	Prior to the expiration of this TO
5	5.4	30 printed copies of the final consensus study report delivered to the TOCOR (see SubTask 5.3)	Prior to the expiration of this TO

**Task 6: Outreach and Dissemination Activities Following Consensus Report (Contract Level PWS Task Area 2)**

EPA is requesting that the NASEM create a summary of the consensus study report's findings in the form of an electronic and print pamphlet or similar and conduct and record a webinar to promote the release of the report.

**SubTask 6.1 Brief summary of consensus study findings on indoor PM<sub>2.5</sub> and practical mitigation solutions**

The NASEM shall create a 2-5 page standalone summary of the impacts of PM<sub>2.5</sub> on

indoor air quality and human health and potential public health intervention strategies based on the findings in the consensus study report. The target audience for the summary report is policy makers, public health professionals, and the general public. This may be in the form of a text summary, graphical summary, or some combination of both. The summary shall be released as an Adobe PDF download to the public via the NASEM website. The TOCOR and alternate TOCOR shall be notified via email of the location of public websites or similar means used to disseminate information to the public during the course of this task, as well as relevant changes to them.

#### **SubTask 6.2 Printed copies of brief summary of consensus study findings**

The NASEM shall deliver 50 professional-quality printed copies of the 2-5 page standalone summary of the consensus study findings (see SubTask 6.1) to the TOCOR.

#### **SubTask 6.3 Consensus study report release webinar**

The NASEM shall conduct a public webinar to publicize the release of the consensus report on indoor PM<sub>2.5</sub> and practical mitigation solutions. NASEM shall set up and manage the webinar and provide any technical support for committee members' participation. The TOCOR and alternate TOCOR shall be notified via email of the date, time, and agenda of the webinar at least one (1) month prior to the event. All communications regarding the public webinar should go through the TOCOR and alternate TOCOR.

#### **SubTask 6.4 Recording of report release webinar**

The consensus study report release webinar (see SubTask 6.3) shall be recorded and made available on the NASEM website. The TOCOR and alternate TOCOR shall be notified via email of the location of public websites or similar means used to disseminate information to the public during the course of this task, as well as relevant changes to them.

#### **SubTask 6.5 Presentations on the report at professional meetings or conferences**

The NASEM shall present on the findings of the consensus study report during two (2) professional meetings or conferences relevant to the study subject. The NASEM shall identify appropriate meetings or conferences, submit presentation proposals, and arrange travel and/or technical support as needed for the presentation. The TOCOR and alternate TOCOR shall be notified via email of the name of each meeting or conference and the date, time, location of the presentation at least one (1) month prior to the events, which must take place prior to the expiration of this TO.

#### **SubTask 6.6 Slides from presentations on the report at professional meetings or conferences**

The NASEM shall provide the TOCOR with an Adobe PDF copy of the slides presented at two (2) professional meetings or conferences (see SubTask 6.5) within one (1) week after the presentation or prior to the expiration of this TO, whichever comes first.

### ***Task 6. Deliverables***

<b>Task</b>	<b>SubTask</b>	<b>Deliverable</b>	<b>Schedule</b>
6	6.1	Brief summary of consensus study report findings in Adobe PDF on NASEM website	At least 5 months prior to expiration of this TO
6	6.2	50 printed copies of brief summary of consensus study report findings (see SubTask 6.1)	Prior to expiration of this TO
6	6.3	Date, time, and agenda of consensus study report release webinar	At least 4 months prior to expiration of this TO, with webinar to be scheduled no later than one month after completion of SubTask 5.2
6	6.4	Recording of report release webinar available on NASEM website	Prior to expiration of this TO
6	6.5	Name, date, time, and location of 2 presentations at professional meetings or conferences	1 month prior to each presentation, which must take place prior to the expiration of this TO
6	6.6	Slides in Adobe PDF as presented at 2 professional meetings or conferences (see SubTask 6.5)	Within 1 week after the presentation or prior to the expiration of this TO, whichever comes first

## **VIII. ACCEPTANCE CRITERIA**

The Contractor shall prepare high quality products and that are reproducible and transparent. Deliverables shall be edited for grammar, spelling, and logic flow. The technical information shall be reasonably complete and presented in a logical, readable manner. Text deliverables including the consensus study report shall be provided in Microsoft Word 2016 and/or Adobe PDF or compatible formats. Webinar recordings with professional-quality audio and video shall be made available to stream from the NASEM website.

ORDER FOR SUPPLIES OR SERVICES						PAGE OF PAGES		
						1	6	
<b>IMPORTANT:</b> Mark all packages and papers with contract and/or order numbers.								
1. DATE OF ORDER 06/03/2021		2. CONTRACT NO. (If any) 68HERC19D0011		6. SHIP TO:				
3. ORDER NO. 68HERC21F0257		4. REQUISITION/REFERENCE NO. See Schedule		a. NAME OF CONSIGNEE  OLEM ORCR				
5. ISSUING OFFICE (Address correspondence to) CAD  US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001				b. STREET ADDRESS One Potomac Yard 2777 S Crystal Drive				
				c. CITY Crystal City		d. STATE VA	e. ZIP CODE 22202-3553	
7. TO: JAMES BURKE				f. SHIP VIA				
a. NAME OF CONTRACTOR National Academy of Sciences				8. TYPE OF ORDER  <input type="checkbox"/> a. PURCHASE REFERENCE YOUR:    Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.				
b. COMPANY NAME								
c. STREET ADDRESS 500 FIFTH STREET NW				<input checked="" type="checkbox"/> b. DELIVERY  Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.				
d. CITY WASHINGTON		e. STATE DC	f. ZIP CODE 200012736					
9. ACCOUNTING AND APPROPRIATION DATA See Schedule				10. REQUISITIONING OFFICE Office of Research and Development				
11. BUSINESS CLASSIFICATION (Check appropriate box(es)) <input type="checkbox"/> a. SMALL <input checked="" type="checkbox"/> b. OTHER THAN SMALL <input type="checkbox"/> c. DISADVANTAGED <input type="checkbox"/> d. WOMEN-OWNED <input type="checkbox"/> e. HUBZone <input type="checkbox"/> f. SERVICE-DISABLED VETERAN-OWNED <input type="checkbox"/> g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM <input type="checkbox"/> h. EDWOSB						12. F.O.B. POINT		
13. PLACE OF		14. GOVERNMENT B/L NO.		15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 12/02/2022		16. DISCOUNT TERMS		
a. INSPECTION Destination		b. ACCEPTANCE Destination						
17. SCHEDULE (See reverse for Rejections)								
ITEM NO. (a)	SUPPLIES OR SERVICES (b)			QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	DUNS Number: 041964057 Request for a new Task Order under NAS Contract #68HERC19D0011 for OLEM/ORCR entitled: "EAF-SLAG Health Study", for \$596,045.66. NOTE: PR-R8-21-00379 \$100,000 and PR-ORD-21-00448 \$596,045.66 Will need Continued ...							
SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT		19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		\$0.00	17(h) TOTAL (Cont. pages) ◀
	21. MAIL INVOICE TO:							
	a. NAME		RTP Finance Center				\$921,046.00	17(i) GRAND TOTAL ◀
	b. STREET ADDRESS (or P.O. Box)		US Environmental Protection Agency RTP-Finance Center (AA216-01) 109 TW Alexander Drive www2.epa.gov/financial/contracts					
c. CITY		d. STATE	e. ZIP CODE					
Durham		NC	27711					
22. UNITED STATES OF AMERICA BY (Signature)				06/03/2021		23. NAME (Typed) William M. Yates TITLE: CONTRACTING/ORDERING OFFICER		



**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

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2

**IMPORTANT:** Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 06/03/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0257
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
0001	<p>to be utilized in EAS for complete funding (Grand Total: \$696,045.66) of New Task Order Request - ALL SUPPORTING DOCUMENTATION WILL BE UPLOADED IN EAS UNDER OLEM PR-ORD-21-00448 New Task Order request under NAS Contract #68HERC19D0011 Task Order #: TBD Title: Consensus Report on Electric Arc Furnace Slag: Understanding Potential Human Health Risks from Unencapsulated Uses CO: Mark Cranley CS: William Yates, Contract Specialist Acquisition Division: CAD Exemption Code (5170 Conference Process): ME262600 TOCOR: Colette Hodes ALTOCOR: Timothy Taylor CL COR: Glennis Reslock ALT CL COR: Jorge Rangel No IT Codes or FITARA necessary. All ORCR invoices should be assigned to the TOCOR and Alternate TOCOR. TOCOR: COLETTE HODES Max Expire Date: 12/02/2022 Admin Office: CAD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001</p> <p>Additional funding required in the amount of \$225,000.34 for a grand total of \$821,046.00 for PR-OLEM-21-00448. Request for a new Task Order under NAS Contract #68HERC19D0011 for OLEM/ORCR entitled: "EAF-SLAG Health Study", for \$596,045.66. NOTE: PR-R8-21-00379 \$100,000 and PR-ORD-21-00448 \$596,045.66 Will need to be utilized in EAS for complete funding (Grand Total: \$696,045.66) of New Task Order Request - ALL SUPPORTING DOCUMENTATION WILL BE UPLOADED IN EAS UNDER OLEM PR-ORD-21-00448 Continued ...</p>					

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$0.00

**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

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3

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 06/03/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0257
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	<p>New Task Order request under NAS Contract #68HERC19D0011</p> <p>Task Order #: TBD</p> <p>Title: Consensus Report on Electric Arc Furnace Slag: Understanding Potential Human Health Risks from Unencapsulated Uses</p> <p>CO: Mark Cranley</p> <p>CS: William Yates, Contract Specialist</p> <p>Acquisition Division: CAD</p> <p>Exemption Code (5170 Conference Process): ME262600</p> <p>TOCOR: Colette Hodes</p> <p>ALTOCOR: Timothy Taylor</p> <p>CL COR: Glennis Reslock</p> <p>ALT CL COR: Jorge Rangel</p> <p>No IT Codes or FITARA necessary.</p> <p>All ORCR invoices should be assigned to the TOCOR and Alternate TOCOR.</p> <p>Requisition No: PR-OLEM-21-00448, PR-R8-21-00379</p> <p>Accounting Info:</p> <p>20-21-B-31C-000DA1-2585-2131CPP009-001</p> <p>BFY: 20 EFY: 21 Fund: B Budget Org:</p> <p>31C Program (PRC): 000DA1 Budget (BOC): 2585 DCN - Line ID: 2131CPP009-001</p> <p>Funding Flag: Complete</p> <p>Funded: \$0.00</p> <p>Accounting Info:</p> <p>21-22-B-31C-000DA1-2585-2131CPP009-002</p> <p>BFY: 21 EFY: 22 Fund: B Budget Org:</p> <p>31C Program (PRC): 000DA1 Budget (BOC): 2585 DCN - Line ID: 2131CPP009-002</p> <p>Funding Flag: Complete</p> <p>Funded: \$0.00</p> <p>Accounting Info:</p> <p>20-21-B-08WCO21-000C95-2532-2108WSW801-001</p> <p>BFY: 20 EFY: 21 Fund: B Budget Org: 08WCO21 Program (PRC): 000C95</p> <p>Budget (BOC): 2532 DCN - Line ID: 2108WSW801-001</p> <p>Funding Flag: Complete</p> <p>Funded: \$10,000.00</p> <p>Accounting Info:</p> <p>Continued ...</p>					
TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))					\$0.00	

**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

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4

**IMPORTANT:** Mark all packages and papers with contract and/or order numbers.

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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
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**ORDER FOR SUPPLIES OR SERVICES**  
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**IMPORTANT:** Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 06/03/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0257
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Funded: \$1,379.28 Accounting Info: 20-21-B-08WCO21-000DA1-2532-2108WSW801 -008 BFY: 20 EFY: 21 Fund: B Budget Org: 08WCO21 Program (PRC): 000DA1 Budget (BOC): 2532 DCN - Line ID: 2108WSW801-008 Funding Flag: Complete Funded: \$2,797.13 Accounting Info: 20-21-B-08WCO21-000DC3-2532-2108WSW801 -009 BFY: 20 EFY: 21 Fund: B Budget Org: 08WCO21 Program (PRC): 000DC3 Budget (BOC): 2532 DCN - Line ID: 2108WSW801-009 Funding Flag: Complete Funded: \$5.69 Accounting Info: 20-21-B-08WCO21-000E44-2532-2108WSW801 -010 BFY: 20 EFY: 21 Fund: B Budget Org: 08WCO21 Program (PRC): 000E44 Budget (BOC): 2532 DCN - Line ID: 2108WSW801-010 Funding Flag: Complete Funded: \$18,628.51 Accounting Info: 20-21-B-08WCO21-000E50-2532-2108WSW801 -011 BFY: 20 EFY: 21 Fund: B Budget Org: 08WCO21 Program (PRC): 000E50 Budget (BOC): 2532 DCN - Line ID: 2108WSW801-011 Funding Flag: Complete Funded: \$11,077.98 Accounting Info: 20-21-B-08WCO21-000E52-2532-2108WSW801 -012 BFY: 20 EFY: 21 Fund: B Budget Org: 08WCO21 Program (PRC): 000E52 Budget (BOC): 2532 DCN - Line ID: 2108WSW801-012 Funding Flag: Complete Funded: \$3,000.00 Accounting Info: 20-21-B-08WCO21-000M90-2532-2108WSW801 -013 BFY: 20 EFY: 21 Fund: B Budget Org: 08WCO21 Program (PRC): 000M90 Budget (BOC): 2532 DCN - Line ID: Continued ...					

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ORDER FOR SUPPLIES OR SERVICES  
SCHEDULE - CONTINUATION

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IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER	CONTRACT NO.	ORDER NO.
06/03/2021	68HERC19D0011	68HERC21F0257

ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	2108WSW801-013 Funding Flag: Complete Funded: \$4,992.28 Accounting Info: 20-21-B-08WCO21-000YF2-2532-2108WSW801 -014 BFY: 20 EFY: 21 Fund: B Budget Org: 08WCO21 Program (PRC): 000YF2 Budget (BOC): 2532 DCN - Line ID: 2108WSW801-014 Funding Flag: Complete Funded: \$4.00					

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$0.00

## PERFORMANCE WORK STATEMENT

National Academy of Sciences (NAS)  
Board on Environmental Studies and Toxicology (BEST)  
Contract #68HERC19D0011  
PR-OLEM-21-00448/PR-R8-21-00379  
Task Order #68HERC21F0257

**I. TITLE:** Consensus Report on Electric Arc Furnace Slag: Understanding Potential Human Health Risks from Unencapsulated Uses

**EAS Short Title:** EAF Slag Health Study

### II. Task Order Contracting Officer Representative(s):

<b>Task Order Contracting Officer Representative (TOCOR)</b> <b>Name:</b> Colette Hodes <b>Office:</b> OLEM/ORCR/PMCAO/ERAS 2777 S Crystal Drive Bldg: Potomac Yard One (South Tower) Room No. S5927, Mail Code: 5305P Arlington, VA 22202  <b>Phone:</b> 703-605-0632 <b>Email:</b> <a href="mailto:hodes.colette@epa.gov">hodes.colette@epa.gov</a>	<b>Alternate Task Order Contracting Officer Representative (Alt. TOCOR)</b> <b>Name:</b> Timothy Taylor <b>Office:</b> OLEM/ORCR/PMCAO/ERAS 2777 S Crystal Drive Bldg: Potomac Yard One (South Tower) Room No. S5947, Mail Code: 5305P Arlington, VA 22202  <b>Phone:</b> 703-308-8451 <b>Email:</b> <a href="mailto:taylor.timothy@epa.gov">taylor.timothy@epa.gov</a>
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**III. PERIOD OF PERFORMANCE:** Date of Task Order award through 18 months following award.

### IV. PURPOSE OF TASK ORDER

The purpose of this task order (TO) is to produce a consensus study report at the request of the U.S Environmental Protection Agency (EPA). The EPA requires the National Academy of Sciences (NAS) Board on Environmental Studies and Toxicology (BEST) to convene an expert committee and conduct a review of existing information and analyses related to electric arc furnace (EAF) slag and to assess human health risks associated with the unencapsulated use of EAF slag.

## V. BACKGROUND

EAF slag is a rock-like material that is created in large quantities during steel production. EAF slag is used in many ways including both encapsulated (e.g., contained in concrete) and unencapsulated ways (e.g., loose ground cover material). EAF slag is marketed as a gravel alternative in at least 19 states and is expected to be used primarily near steel production sites to minimize transportation costs. The cost of EAF slag is often less than a quarter that of quarried gravel. A preliminary review of the location of EAF steel production facilities found that the surrounding poverty rates were 2-3x the national average, suggesting that EAF slag may be used predominantly in lower income areas.

EAF slag is known to contain higher levels of metals than gravel and other types of slag from steel production (i.e., basic oxygen furnace and blast furnace). EPA has found EAF slag used in driveways and as groundcover can exceed soil screening levels for both manganese and hexavalent chromium. Some states have conducted screening-level risk assessments for unencapsulated EAF slag use and determined risk mitigation measures were needed to prevent potential risks to children and nearby residents. A more refined risk assessment developed by an industry-sponsored consulting firm found no risks to human health when evaluating a dry terrestrial environment. Areas of uncertainty in risk assessments include the effects of aging slag in the environment; the durability of slag under compression and the potential to release encased metals; exposure associated with residential applications; and the cancer and non-cancer toxicity of the metals found in slag.

EAF slag, when initially tested using the Toxicity Characteristic Leaching Procedure (TCLP, acidic conditions), has not been found to be classifiable as a hazardous waste under the Resource Conservation and Recovery Act. There is variability in state regulation of EAF slag. For instance, some states identify EAF slag as solid waste and others do not (classifying it as a product). Some states place restrictions on unencapsulated uses (e.g. not allowed in residential settings) and others do not. EPA has developed a *Methodology for Evaluating the Beneficial Use of Industrial Non-Hazardous Secondary Materials*<sup>1</sup> and a *Beneficial Use Compendium*<sup>2</sup> for states and other entities to use to help improve the consistency and quality of beneficial use evaluations. When possible, safe beneficial use of non-hazardous secondary materials is an environmentally preferable option to disposal, such as placing them in a landfill, in order to conserve natural resources and reduce climate impacts.

EPA's mission is to protect human health and to safeguard the natural environment-air, water, and land-upon which life depends. EPA uses the best available science to determine when action may be needed under the statutes implemented by the Agency in order to address human health and environmental concerns. EPA is seeking NAS BEST input to assess potential

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<sup>1</sup> [https://www.epa.gov/sites/production/files/2016-10/documents/methodology\\_for\\_evaluating\\_beneficial\\_use\\_of\\_secondary\\_materials\\_4-14-16.pdf](https://www.epa.gov/sites/production/files/2016-10/documents/methodology_for_evaluating_beneficial_use_of_secondary_materials_4-14-16.pdf)

<sup>2</sup> [https://www.epa.gov/sites/production/files/2016-10/documents/beneficial\\_use\\_compendium\\_text\\_and\\_appendix\\_6-22-16.pdf](https://www.epa.gov/sites/production/files/2016-10/documents/beneficial_use_compendium_text_and_appendix_6-22-16.pdf)

human health risks associated with unencapsulated EAF slag use; risks associated with residential uses such as landscaping/xeriscaping; the magnitude of any risks; uncertainties related to EAF slag exposure and toxicity that may affect risk conclusions; and the potential impact of these uncertainties on the magnitude and understanding of potential EAF slag risks.

## **VI. SCOPE OF WORK**

The NAS Study Process (<https://www.nationalacademies.org/about/our-study-process>) is sufficient justification that NAS shall produce a scientific information product that is consistent with the Agency's information quality standards, the Federal Advisory Committee Act, and transparent and reproducible as defined by the Office of Management and Budget. NAS shall ensure the report produced is compliant with the Agency quality standards. Secondary data must be rigorously evaluated, and the review of underlying sources in the development of the NAS report must include evaluation of the data sources, consideration of their relevance and include acceptance criteria used for the study selection.

### **Expertise Required**

NAS shall identify a proposed group of subject matter experts (SME) to serve on the committee who are recognized experts in the fields relevant to the request including: risk assessment, exposure assessment, epidemiology, relevant specialty areas in toxicology, public health, chemistry, environmental engineering, and fate and transport of chemicals in the environment.

The NAS expert committee shall, at a minimum, incorporate information collected from its evaluation of unencapsulated EAF slag (shortened to “EAF slag” from here forward) risks including the following:

- Reports and publications on the composition of EAF slag
- Current regulation of EAF slag
- Available information on the use of EAF slag
- Relevant risk assessments, especially for the constituents of highest potential risk in EAF slag
- Published toxicology and epidemiological studies, especially for the constituents of highest concern in EAF slag
- Demographic information on EAF slag production/use areas

### **Charge to the Expert Committee**

The Committee will conduct a review of existing information and analyses to assess human health risks associated with the use of unencapsulated EAF slag. As part of its assessment and to the extent sufficient data are available, the committee will address the following aspects with respect to potential human health effects associated from unencapsulated use of EAF slag:



- Chemical, physical, and geotechnical properties of EAF slag (including, but not limited to chemical concentrations, particle size distribution, soundness, compressive strength, and abrasion resistance), including how those properties might change over time and vary across the types of EAF slag produced at different steel production facilities in the United States.
- Relative quantities and general locations for the different beneficial uses of EAF slag, including uses in the proximity of residential areas.
- Exposure levels for substances found in EAF slag that are associated with adverse effects observed in epidemiological studies, and how those levels compare with potential exposures through EAF slag use, including residential uses.
- Population subgroup characteristics and human developmental stages expected to be associated with the highest sensitivity to exposure to EAF slag constituents.
- Relevant existing cancer and/or non-cancer toxicity values for inhalation and oral exposures to manganese, hexavalent chromium, and other constituents that might drive risks associated with EAF slag use.
- Uncertainties associated with existing toxicity benchmarks. Consider advances in the scientific understanding of hexavalent chromium and manganese toxicology since the establishment of existing toxicity benchmarks. Are sensitive populations and background exposure to essential nutrients such as manganese adequately accounted for in existing toxicity benchmarks?
- Pathways, routes, and scenarios expected to be most important in evaluating exposure to toxic constituents of EAF slag. Are toxic constituents of EAF slag likely to be bioavailable from unencapsulated uses?
- Effects of weathering and wear (e.g., from vehicular traffic) of unencapsulated EAF slag on the duration and magnitude of human exposure to toxic constituents. Also, consider the possible effects of the formation of smaller particle sizes with respect to exposure.
- Relationships between EAF slag uses and human health risk, including consideration of factors, such as land use settings, human behavior, geographic areas, and local climate that may lead to the highest risks.
- Whether cumulative exposures to stressors associated with lower-socioeconomic living conditions are likely to exacerbate health risks of EAF slag constituents, including the risk of negative cognitive effects.

- Considering the overall understanding of human health risk associated with EAF slag use, identify research needed to address information gaps regarding the toxicity of EAF slag constituents and human exposures to the most toxic constituents.
- To the extent possible, provide a concise characterization of the risks to human health associated with EAF slag use.

## **VII. DESCRIPTION OF TASKS**

### **Task 1: Kick-off Call, Teleconferences, Meeting Summaries, and Monthly Progress Reports (Contract Level PWS Task Area 2)**

#### *SubTask 1.1 - Kick-off Call*

EPA is requesting NAS to convene teleconferences to understand EPA's need for an EAF Slag Study.

The NAS BEST shall convene a Kick-off Call teleconference with the TOCOR and relevant EPA staff to review the objectives, technical requirements, and schedule for the consensus study report on Electric Arc Furnace Slag: Understanding Potential Human Health Risks from Unencapsulated Uses to develop a full understanding of EPA's needs to ensure the development of a useful product. The Kick-off Call shall occur within seven (7) business days of acceptance of this task order on a mutually agreeable date.

#### *SubTask 1.2 - Regular Meetings and Written Summaries*

Working with the TOCOR, set up appropriate meetings with EPA personnel to develop a full understanding of EPA's needs to ensure the development of a useful product. After the Kick-off Call, monthly telephone or online meetings shall be scheduled. Starting with the Kick-off Call, NAS shall provide written summaries of each call or meeting as part of the monthly progress report (see Subtask 1.3).

#### *SubTask 1.3 - Written Monthly Progress Reports*

Written monthly progress reports shall include work completed during the month, work projected for the next month, a summary of expenditures for the period, and cumulative expenditures through the end of the reporting period. The written progress reports shall be delivered via email to the TOCOR, Contract Level Contracting Officer Representative (CL COR), and Contracting Officer (CO).

### **Task 1. Deliverables**

Task	SubTask	Deliverable	Schedule
1	1.1	Kick-off Conference Call	Within 7 business days of TO initiation
1	1.2	Meeting summaries	With each monthly progress report
1	1.3	Monthly Progress Reports	Monthly after TO initiation

### **Task 2: Committee Selection of Subject Matter Experts (Contract Level PWS Task Area 2)**

The NAS shall establish an ad hoc committee of approximately fifteen (15) recognized experts in the technical fields relevant to the study including steel industry slag production and use, environmental transport and transformation, engineering, hydrogeochemistry, environmental sampling and analysis, toxicology, epidemiology, biostatistics, exposure science (multiple pathways and routes), public health, sociology, risk assessment, and stormwater management. The committee might include a member from a European or other foreign country who has relevant expertise in assessing risks associated with the use of unencapsulated EAF slag. The EPA may offer suggestions of potential committee members to be considered by the National Academies during its nominations process. EPA may also comment on the proposed committee membership during the 20-day comment period following announcement of the provisional committee. The National Academies will select the committee members.

Nominations for committee membership will be sought from a broad range of sources, including academia, non-governmental/public interest organizations, private industry, and federal, state, tribal, and local governments. Membership in the NAS, NAE, or NAM and previous involvement in National Academies studies are taken into account in committee selection. The inclusion of women, minorities, and young professionals and geographic diversity are additional considerations. The committee shall be formed in accordance with the National Academies policies concerning conflict of interest and bias to ensure a balanced and objective study

### **Task 2. Deliverables**

Task	SubTask	Deliverable	Schedule
2	N/A	List of provisional committee members including biographical sketches	Within 90 days of TO initiation

### **Task 3: Committee Meetings, Information Gathering, Deliberations, and Drafting the Report (Contract Level PWS Task Area 2)**

An ad hoc committee of about 15 members shall hold at least four meetings, which shall include at least two public sessions to hear presentations from EPA personnel and receive input from relevant outside experts. In addition to providing invited

presentations, the public information gathering sessions shall be designed to enable committee members to discuss key topics with meeting participants.

The committee meetings shall also include closed sessions for deliberation and report development. The committee shall conduct meetings, including the public sessions, as virtual meetings if in-person meetings are not feasible. The work plan currently includes in person meetings, but these may be replaced by multiple shorter virtual meetings. NAS project staff shall give designated EPA personnel ample advance notice of the public sessions that shall be held in pursuit of this task.

A paid consultant might work under the direction of the committee to carry out literature searches, extract and compile relevant information, and perform preliminary analyses to inform the committee's deliberations.

The committee shall evaluate the data used in its report, including the relevance of the data sources and acceptance criteria used for study selection. The committee's draft report shall be reviewed in accordance with National Academies' policies and procedures.

*SubTask - 3.1 Committee Teleconferences and Public Information Gathering Meeting-Announcement of public meeting*

The NAS shall organize the initial public committee meeting/workshop regarding the subject of the charge to the committee. Within 100 days of TO initiation, there shall be an announcement of the first public meeting and a request for the submission of information by outside parties at least 30 days prior to the meeting.

*SubTask - 3.2 Hold public meeting*

The NAS shall arrange for the participation of the experts, the initial public committee meeting/workshop within 150 days of the TO initiation. Arrangement and provision of logistical support for the experts' participation in the public committee meetings(s)/workshop(s) or web conferencing services allowing for expert discussion, display of presentation materials, public viewing and participation (including questions), and recording and future availability of these materials and recordings on the NAS website is required.

*SubTask - 3.3 Make meeting submissions and summaries publicly available*

The NAS shall also arrange for the participation of committee members and invited expert speakers in subsequent meetings and/or conference calls. Arrangement and provision of logistical support for the experts' participation in the meetings and/or conference calls shall be provided by NAS.

After the initial public meeting, the committee may deliberate in meetings closed to the public to develop draft findings and recommendations free from outside influences. The public shall be provided with brief summaries of these meetings that include the list of committee members present. The committee may also hold additional public information gathering meetings if deemed necessary.

The NAS shall maintain a public “docket,” available through the NAS website or Public Access Files, that contains written public comments and presentations for the aforementioned meetings/workshops as well as meeting summaries.

### ***Task 3. Deliverables***

<b>Task</b>	<b>SubTask</b>	<b>Deliverable</b>	<b>Schedule</b>
3	3.1	Announcement of public meeting	Within 100 days of TO initiation
3	3.2	Hold public meeting	Within 150 days of TO initiation
3	3.3	Make meeting submissions and summaries publicly available	Within 180 days of TO initiation for first public meeting, and 15 business days of subsequent meetings

### **Task 4: Report (Contract Level PWS Task Area 2)**

The committee shall strive to develop a consensus report that is specific in its description of the risks presented by the uses and exposures described in the background section above (i.e., characterization of any human health risks associated with unencapsulated EAF slag use; the risks associated with residential uses such as landscaping/xeriscaping; characterization of uncertainties related to EAF slag exposure and toxicity that may affect risk conclusions; and the potential impact of these uncertainties on the magnitude and understanding of potential EAF slag risks).

#### ***SubTask 4.1 – Prepublication report***

The NAS shall deliver the prepublication consensus report presenting the NAS committee’s findings and recommendations regarding the charge of the committee and summarizing the process followed by the committee to develop those findings and recommendations within 14 months of the TO award. The committee shall strive to develop consensus where possible while describing the range of views for issues where a consensus cannot be reached.

#### ***SubTask 4.2 - Briefing for senior EPA leadership on report***

EPA requires that NAS provide a briefing for senior EPA Office of Land and Emergency Management (OLEM), and EPA Region 8 leadership on the report, including participation from the Committee members, prior to the public release of the report. The prepublication report shall be submitted to EPA 10 business days prior to public release. Briefings shall be provided to the sponsor (EPA) at least three days before public dissemination of the report and not later than three days before the end of the period of performance.

#### ***SubTask 4.3 - 20 bound copies of consensus report***

The NAS shall deliver twenty (20) bound hard copies of the final report to the TOCOR within 18 months of task order initiation.

*SubTask 4.4 - Free, downloadable Final Consensus Report on the NAS website*

The final consensus report should be completed and made publicly available no later than the end of the 18-month period of performance. The report shall be made freely available on the National Academies website within 18 months of TO initiation. Other dissemination activities (e.g., briefings and webinars) shall be planned to ensure that the report results are widely disseminated.

**Task 4. Deliverables**

Task	SubTask	Deliverable	Schedule
4	4.1	Prepublication final consensus report in electronic format	Within 14 months of TO initiation
4	4.2	Briefing for senior EPA leadership on report	The prepublication report shall be submitted to EPA 10 business days prior to public release. Briefings shall be provided to the sponsor (EPA) at least three days before public dissemination the report and not later than three day before the end of the period of performance.
4	4.3	20 bound copies of consensus report	Within 18 months of TO initiation
4	4.4	Free, downloadable consensus report on the NAS website	Upon public release, within 18 months TO initiation

**VIII. ACCEPTANCE CRITERIA**

The Contractor shall prepare high quality products that are reproducible and transparent. Figures submitted shall be of high quality similar to presentations developed for national scientific forums. Deliverables shall be edited for grammar, spelling, and logic flow. The technical information shall be reasonable, complete and presented in a logical, readable manner. Text deliverables including the consensus study report shall be provided in Microsoft Word 2016 and/or Adobe PDF or compatible format.

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>				1. CONTRACT ID CODE		PAGE OF PAGES	
						1      2	
2. AMENDMENT/MODIFICATION NO.		3. EFFECTIVE DATE		4. REQUISITION/PURCHASE REQ. NO.		5. PROJECT NO. (If applicable)	
P00001		See Block 16C					
6. ISSUED BY		CODE		7. ADMINISTERED BY (If other than Item 6)		CODE	
CAD							
CAD							
US Environmental Protection Agency							
26 West Martin Luther King Drive							
Mail Code: W136							
Cincinnati OH 45268-0001							
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)				(x)		9A. AMENDMENT OF SOLICITATION NO.	
National Academy of Sciences							
Attn: JAMES BURKE							
500 FIFTH STREET NW						9B. DATED (SEE ITEM 11)	
WASHINGTON DC 200012736							
				x		10A. MODIFICATION OF CONTRACT/ORDER NO.	
						68HERC19D0011	
						68HERC21F0257	
						10B. DATED (SEE ITEM 13)	
CODE 041964057				FACILITY CODE		06/03/2021	
<b>11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS</b>							
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers <input type="checkbox"/> is extended. <input type="checkbox"/> is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.							
12. ACCOUNTING AND APPROPRIATION DATA (If required)							
See Schedule							
<b>13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.</b>							
CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.						
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).						
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:						
	D. OTHER (Specify type of modification and authority)						
<b>E. IMPORTANT:</b> Contractor <input checked="" type="checkbox"/> is not <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.							
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)							
DUNS Number: 041964057							
Request for a new Task Order under NAS Contract #68HERC19D0011 for OLEM/ORCR entitled:							
"EAF-SLAG Health Study", for \$596,045.66. NOTE: PR-R8-21-00379 \$100,000 and PR-ORD-21-00448							
\$596,045.66 Will need to be utilized in EAS for complete funding (Grand Total: \$696,045.66)							
of New Task Order Request -							
ALL SUPPORTING DOCUMENTATION WILL BE UPLOADED IN EAS UNDER OLEM PR-ORD-21-00448							
New Task Order request under NAS Contract #68HERC19D0011							
Task Order #: TBD							
Title: Consensus Report on Electric Arc Furnace Slag: Understanding Potential Human Health							
Risks from Unencapsulated Uses							
CO: Mark Cranley							
Continued ...							
Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.							
15A. NAME AND TITLE OF SIGNER (Type or print)				16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)			
				William M. Yates			
15B. CONTRACTOR/OFFEROR		15C. DATE SIGNED		16B. UNITED STATES OF AMERICA		16C. DATE SIGNED	
				 (Signature of Contracting Officer)		ELECTRONIC SIGNATURE 06/09/2021	
(Signature of person authorized to sign)							

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 68HERC19D0011/68HERC21F0257/P00001	PAGE	OF
		2	2

NAME OF OFFEROR OR CONTRACTOR  
National Academy of Sciences

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>CS: William Yates, Contract Specialist Acquisition Division: CAD Exemption Code (5170 Conference Process): ME262600 TOCOR: Colette Hodes ALTOCOR: Timothy Taylor CL COR: Glennis Reslock ALT CL COR: Jorge Rangel No IT Codes or FITARA necessary. All ORCR invoices should be assigned to the TOCOR and Alternate TOCOR. TOCOR: COLETTE HODES Max Expire Date: 12/02/2022 LIST OF CHANGES: Reason for Modification: The purpose of this Administrative Modification will be to reflect the period of performance within the EAS system. All other conditions remain the same.</p> <p>Period Of Performance Start Date Added : 06/03/2021 Period Of Performance End Date Added : 12/02/2022</p> <p>Payment: RTP Finance Center US Environmental Protection Agency RTP-Finance Center (AA216-01) 109 TW Alexander Drive www2.epa.gov/financial/contracts Durham NC 27711 Period of Performance: 06/03/2021 to 12/02/2022</p>				



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					1 3		
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P00002		See Block 16C		PR-OLEM-21-00448			
6. ISSUED BY		CODE		7. ADMINISTERED BY (If other than Item 6)		CODE	
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12. ACCOUNTING AND APPROPRIATION DATA (If required)				Net Increase:		\$821,046.00	
See Schedule							
<b>13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.</b>							
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		C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:					
		D. OTHER (Specify type of modification and authority)					
<b>E. IMPORTANT:</b> Contractor <input checked="" type="checkbox"/> is not <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.							
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(Signature of person authorized to sign)							

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NAME OF OFFEROR OR CONTRACTOR  
National Academy of Sciences

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>CS: William Yates, Contract Specialist Acquisition Division: CAD Exemption Code (5170 Conference Process): ME262600 TOCOR: Colette Hodes ALTOCOR: Timothy Taylor CL COR: Glennis Reslock ALT CL COR: Jorge Rangel No IT Codes or FITARA necessary. All ORCR invoices should be assigned to the TOCOR and Alternate TOCOR. TOCOR: COLETTE HODES Max Expire Date: 12/02/2022 LIST OF CHANGES: Reason for Modification: This modification will correct the amount that should be reflected in the COMPAS system and show this task order as correctly funded in the amount of \$921,046.00. The funding for PR-OLEM-21-00448 which was not pulled into the funding on the base task order will be incorporated by this modification. The funding will be included on this modification so the rest of the funding in the amount of \$821,046 will be pulled in so the total funding of \$921,046.00 will be reflected in the COMPAS and EAS system.</p> <p>New Total Amount for this Version: \$921,046.00 New Total Amount for this Award: \$921,046.00 Obligated Amount for this Modification: \$821,046.00 New Total Obligated Amount for this Award: \$921,046.00</p> <p>Incremental Funded Amount changed: from \$100,000.00 to \$921,046.00</p> <p>CHANGES FOR LINE ITEM NUMBER: 1 Obligated Amount for this Modification: \$821,046.00 Incremental Funded Amount changed from \$100,000.00 to \$921,046.00</p> <p>NEW ACCOUNTING CODE ADDED: Account code: 20-21-B-31C-000DA1-2585-2131CPP009-001 Beginning FiscalYear 20 Ending Fiscal Year 21 Fund (Appropriation) B Budget Organization 31C Program (PRC) 000DA1 Continued ...</p>				

<b>CONTINUATION SHEET</b>	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE	OF
	68HERC19D0011/68HERC21F0257/P00002	3	3

NAME OF OFFEROR OR CONTRACTOR  
National Academy of Sciences

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>Budget (BOC) 2585 Job # (Site/Project) Cost Organization DCN-LineID 2131CPP009-001</p> <p>Amount: \$336,833.39</p> <p>NEW ACCOUNTING CODE ADDED: Account code: 21-22-B-31C-000DA1-2585-2131CPP009-002 Beginning FiscalYear 21 Ending Fiscal Year 22 Fund (Appropriation) B Budget Organization 31C Program (PRC) 000DA1 Budget (BOC) 2585 Job # (Site/Project) Cost Organization DCN-LineID 2131CPP009-002</p> <p>Amount: \$484,212.61</p> <p>Payment Address: RTP Finance Center US Environmental Protection Agency RTP-Finance Center (AA216-01) 109 TW Alexander Drive www2.epa.gov/financial/contracts Durham NC 27711</p> <p>Payment: RTP Finance Center US Environmental Protection Agency RTP-Finance Center (AA216-01) 109 TW Alexander Drive www2.epa.gov/financial/contracts Durham NC 27711 Period of Performance: 06/03/2021 to 12/02/2022</p>				

## ORDER FOR SUPPLIES OR SERVICES

PAGE OF PAGES

1

3

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER 09/07/2021		2. CONTRACT NO. (If any) 68HERC19D0011		6. SHIP TO: a. NAME OF CONSIGNEE Office of Research and Development	
3. ORDER NO. 68HERC21F0401		4. REQUISITION/REFERENCE NO. PR-ORD-21-01009			
5. ISSUING OFFICE (Address correspondence to) CAD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001				b. STREET ADDRESS US Environmental Protection Agency 1200 Pennsylvania Avenue, NW MC: 8101R	
				c. CITY Washington	d. STATE DC
				e. ZIP CODE 20460	
7. TO: JAMES BURKE				f. SHIP VIA	
a. NAME OF CONTRACTOR National Academy of Sciences					
b. COMPANY NAME				8. TYPE OF ORDER	
c. STREET ADDRESS 500 FIFTH STREET NW				<input type="checkbox"/> a. PURCHASE REFERENCE YOUR:   Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.	
d. CITY WASHINGTON				e. STATE DC	f. ZIP CODE 200012736
9. ACCOUNTING AND APPROPRIATION DATA See Schedule				10. REQUISITIONING OFFICE Office of Research and Development	
11. BUSINESS CLASSIFICATION (Check appropriate box(es)) <input type="checkbox"/> a. SMALL <input checked="" type="checkbox"/> b. OTHER THAN SMALL <input type="checkbox"/> c. DISADVANTAGED <input type="checkbox"/> d. WOMEN-OWNED <input type="checkbox"/> e. HUBZone <input type="checkbox"/> f. SERVICE-DISABLED VETERAN-OWNED <input type="checkbox"/> g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM <input type="checkbox"/> h. EDWOSB					
12. F.O.B. POINT					
13. PLACE OF a. INSPECTION Destination		b. ACCEPTANCE Destination		14. GOVERNMENT B/L NO.	
				15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 03/06/2023	
				16. DISCOUNT TERMS	

## 17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	DUNS Number: 041964057 TOCOR: VICKI SOTO Max Expire Date: 03/06/2023  Continued ...					

SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT		19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		17(h) TOTAL (Cont. pages)
	21. MAIL INVOICE TO:						
	a. NAME RTP Finance Center		\$612,809.00				17(i) GRAND TOTAL
	b. STREET ADDRESS (or P.O. Box) US Environmental Protection Agency RTP-Finance Center (AA216-01) 109 TW Alexander Drive www2.epa.gov/financial/contracts		\$612,809.00				
c. CITY Durham		d. STATE NC	e. ZIP CODE 27711				

22. UNITED STATES OF

AMERICA BY (Signature)

09/07/2021

ELECTRONIC  
SIGNATURE

23. NAME (Typed)

William M. Yates

TITLE: CONTRACTING/ORDERING OFFICER

**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

PAGE NO  
2

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 09/07/2021	CONTRACT NO. 68HERC19D0011	ORDER NO. 68HERC21F0401
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
0001	<p>Admin Office: CAD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001 Period of Performance: 09/07/2021 to 03/06/2023</p> <p>New Task Order Request under NAS Contract #68HERC19D0011. Funding for New NAS Task Order - Title: "NAS Independent External Peer Review of EPA's Draft Assessment Product - 2021" Total New Task Order Request Amount: \$389,857.54 NAS Contract: 68HERC19D0011 TO No.: TBD TOCOR: Vicki Soto ALTOCOR: Dahnish Shams CO: Mark Cranley CS: William Yates Acquisition Division: CAD Exemption Code (5170 Conference Process): ME262600 CL COR: Glennis Reslock ALT CL COR: Jorge Rangel NO IT Codes or FITARA necessary Product/Service Code: R499</p> <p>Accounting Info: 21-22-C-26D1000-000FK9-2532-26A5C-2126 D1C012-001 BFY: 21 EFY: 22 Fund: C Budget Org: 26D1000 Program (PRC): 000FK9 Budget (BOC): 2532 Cost: 26A5C DCN - Line ID: 2126D1C012-001 Funding Flag: Complete Funded: \$300,000.00 Accounting Info: 21-22-C-26D1000-000FK8-2532-26A5C-2126 D1C012-002 BFY: 21 EFY: 22 Fund: C Budget Org: 26D1000 Program (PRC): 000FK8 Budget (BOC): 2532 Cost: 26A5C DCN - Line ID: 2126D1C012-002 Funding Flag: Complete Funded: \$312,809.00 Continued ...</p>				612,809.00	

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$612,809.00

ORDER FOR SUPPLIES OR SERVICES  
SCHEDULE - CONTINUATION

PAGE NO  
3

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER  
09/07/2021

CONTRACT NO.  
68HERC19D0011

ORDER NO.  
68HERC21F0401

ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$0.00

## PERFORMANCE WORK STATEMENT

National Academy of Sciences (NAS)

Contract #68HERC19D0011

PR-ORD-21-01009

Task Order #68HERC21F0401

**I. TITLE:** NAS Independent External Peer Review of EPA's Draft Assessment Product – 2021

### II. Task Order Contracting Officer Representative(s):

<b>Task Order Contracting Officer Representative (TOCOR)</b> <b>Name:</b> Vicki Soto <b>Office:</b> ORD/CPHEA/CPAD William Jefferson Clinton Building 1200 Pennsylvania Avenue, N.W. Mail Code: 8602R, Room No. 71205 Washington, DC 20460  <b>Phone:</b> (202) 564-3077 <b>Email:</b> <a href="mailto:soto.vicki@epa.gov">soto.vicki@epa.gov</a>	<b>Alternate Task Order Contracting Officer Representative (Alt. TOCOR)</b> <b>Name:</b> Dahnish Shams <b>Office:</b> ORD/CPHEA/CPAD William Jefferson Clinton Building 1200 Pennsylvania Avenue, N.W. Mail Code: 8602R, Room No. 71204 Washington, DC 20460  <b>Phone:</b> (202) 564-2758 <b>Email:</b> <a href="mailto:shams.dahnish@epa.gov">shams.dahnish@epa.gov</a>
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**III. PERIOD OF PERFORMANCE:** Date of Task Order award through 18 months following award.

### IV. PURPOSE OF TASK ORDER

The purpose of this task order (TO) is to engage with the scientific community to address key science issues pertinent to the development of human health assessments. This TO will provide one (1) expert peer review of a formaldehyde draft assessment document.

### V. BACKGROUND

EPA's Center for Public Health and Environmental Assessment (CPHEA) is a leader in the science of human health and environmental risk assessments. CPHEA champions the development and use of health and environmental assessments by interacting with other agencies, the scientific community, industry, policymakers, and the public. The NAS is widely viewed as an impartial, knowledgeable, and respected organization, capable of ensuring audience acceptance of products with which it is associated. The NAS is also able to provide EPA access to a wide range of scientific, expert reviewers and can independently vet such experts for conflicts of interests and a lack of impartiality.

### VI. SCOPE OF WORK

The NAS shall recruit subject-matter experts to provide external peer review of an EPA draft assessment document. NAS' identified peer reviewers shall conduct a peer-review of the draft EPA assessment of formaldehyde. EPA is seeking NAS' advice on the clarity and scientific underpinnings of the overall EPA assessment. EPA's draft assessment includes a hazard identification analysis, which summarizes the chemical properties, toxicokinetics, and health effects associated with exposure, and dose-response analysis, which characterizes the quantitative relationship between chemical exposure and each credible

health hazard. These quantitative relationships are then used to derive cancer and noncancer toxicity values (e.g., inhalation unit risk, reference concentration). The NAS peer review committee is charged by EPA to consider whether the conclusions presented in the draft assessment are clearly presented and scientifically supported. NAS shall develop a peer review report summarizing its findings on the conclusions presented by EPA and recommend ways in which the EPA assessment may be strengthened. NAS shall not assess the human health effects of formaldehyde separately from the IRIS assessment. The NAS previously conducted a peer review of the IRIS assessment of formaldehyde in 2010-2011. While the 2010 draft is of similar length, the current assessment represents an entirely new draft developed de novo using systematic review methods and in a manner responsive to NAS comments on the prior draft. More information on the assessment and its history can be found on the IRIS website: [https://cfpub.epa.gov/ncea/iris\\_drafts/recordisplay.cfm?deid=223614](https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614).

### **Task 1 - Review of EPA's Draft Assessment Document (Contract Level PWS Task Area 1 and Task Area 5)**

EPA requests that NAS perform an expert external peer review on one (1) draft CPHEA assessment (i.e., Integrated Risk Information System (IRIS) Toxicological Review of Formaldehyde plus supplemental appendices) evaluating whether the scientific literature was adequately evaluated by EPA, and whether appropriate methods were used to synthesize the current state-of-the science. In all cases, the project shall operate in a manner consistent with the NAS consensus study process (see: <https://www.nationalacademies.org/about/our-study-process>). The NAS expert peer review committee shall evaluate the assessment's conclusions using the charge questions set forth by EPA and shall not conduct an independent assessment separately from the IRIS document nor shall the NAS comment on the broader aspects of the IRIS Program. Comments provided by the NAS committee shall be limited to responding to the materials provided by the EPA. EPA will provide all documentation (e.g., toxicological review, supplemental documents) in PDF format and grant any access to tools relevant for the review to the peer review panel. Additional background information may be provided to the committee. These materials shall not be reviewed by the NAS, but may be informative as the committee deliberates. Assessment documents will be found via the IRIS website at [https://cfpub.epa.gov/ncea/iris\\_drafts/recordisplay.cfm?deid=223614](https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614). If necessary, EPA will provide a one-pager with the necessary background information. NAS shall coordinate with the EPA prior to initiating Task 1 and notify EPA prior to any public notifications and/or actions. Task 1 will consist of three (3) subtasks.

#### ***Subtask 1.1. – Establish expert panel***

Prior to the initiation of the peer review and immediately upon award of this task order, NAS shall establish an expert panel of up to 12 experts following their procedures on committee composition, balance, and conflict of interest. NAS shall take public nominations for panel members and solicit comments on the panel. The NAS shall form a committee of experts approximately 3 months from the award of this task order. Recommended areas of expertise include the following:

- Public health risk assessment expertise, especially current experience supporting regulatory decisions in the context of the available scientific information for public health and environmental protection (e.g., international or state risk assessors). It would be preferable if this expert(s) has demonstrated experience with systematic review methods for environmental exposures;



- Environmental/occupational epidemiology, especially in the areas of cancer, reproductive, asthma and other immunological effects, and respiratory effects (i.e., multiple experts are needed);
- Toxicology, especially in the areas of cancer, respiratory effects, neurotoxicology, and/or reproductive/developmental toxicology. At least one of these experts should have experience with biological modeling (e.g., toxicokinetic/dosimetric modeling);
- Exposure measures for observational epidemiology studies of environmental and occupational exposures; and
- Dose-response analysis of environmental chemicals, especially current experience with data analysis for human exposure studies, including observational studies.

***Subtask 1.2. – Conduct an independent external peer review and convene public meeting(s)***

EPA requests that NAS conduct an independent external peer review of the draft CPHEA assessment or assessment materials. In coordination with NAS, EPA will transmit charge questions, along with the external peer review draft assessment materials and public comments received, prior to the peer review. NAS shall commence the peer review upon receipt of the assessment materials. EPA will also provide to NAS the public comments submitted on the draft assessment for the committee to consider as background information during their review. EPA also requests that NAS organize a public external peer review meeting(s) for the peer review panel to discuss the draft assessment with EPA. The public peer review meeting(s) shall not exceed 8 total hours and shall include an opportunity for written and oral public comments to the external peer review committee.

***Subtask 1.3. – Prepare Panel Report Based upon listed Tier Levels***

The NAS expert peer review committee shall develop a final report on their review and evaluation of the EPA document. The pre-publication report must be delivered no later than eleven (11) months upon initiation of the peer review (approximately 8 month study development, approximately 3 month quality peer review). Committee formation shall occur separately under subtask 1.1. Within the peer review report, the NAS shall promote clarity and the timely completion of the draft CPHEA assessment materials (e.g., Toxicological Review) by prioritizing and/or tiering recommendations provided to EPA under the following system:

*Tier 1: Recommended Revisions*— Important revisions for EPA to consider and address in order to improve the critical scientific concepts, issues, and/or narrative within the assessment.

*Tier 2: Suggested Revisions* – Revisions that are encouraged to strengthen or clarify the scientific concepts, issues, and/or narrative within the assessment but are not critical. Other factors (e.g., Agency practice and resources) may need to be considered by EPA before undertaking these revisions.

*Tier 3: Future Considerations*— Useful and potentially informative scientific exploration that may inform future evaluations of key science issues and/or inform the development of future assessments. These recommendations are likely outside the immediate scope and/or needs of the assessment under review.

## **VIII. Deliverables**

The products of the NAS tasks for activity are as follows:

- a) EPA requests that written progress reports be provided to the Contracting Officer (CO), Contract Level Contracting Officer Representative (CL COR), and Task Order Contracting Officer Representative (TOCOR) quarterly and include updates on meetings and project milestones.
- b) Task 1, Subtask 1.2. - For all public meetings requested, the CO, CL COR, and TOCOR shall be informed via email of the time, location, and agenda of the meeting 45 days, or as early as practicable, prior to the meeting. All communications regarding public meetings should go through the CO, CL COR, and TOCOR. The NAS shall provide EPA with a final list of all meeting attendees and public commenters within five (5) business days after the meeting. If necessary, arrangement and provision of transportation, lodging, and any other logistical support for the experts' participation shall be provided. If public websites or similar means are used to disseminate information to the public during the course of this task, the CO and TOCOR shall be notified of the location of such information (e.g., websites), as well as relevant changes to them.
- c) Task 1, Subtask 1.3. - The primary products for each review are expected to be: (a) proposed and final lists of experts including biographical sketches, (b) written confirmation that review of potential COI and partiality issues for each expert was completed in accordance with NAS procedures, (c) any submitted public comments, and (d) a final peer review report.

## **IX. ACCEPTANCE CRITERIA**

The Contractor shall prepare high quality products that are reproducible and transparent. Figures submitted shall be of high quality similar to presentations developed for national scientific forums and should be formatted as jpeg or TIFF files. Deliverables shall be edited for grammar, spelling, and logic flow, as well as, technical accuracy, completeness, timeliness, grammatically correct, free of typographical errors, and conformance with the specific task, charge and expertise and deliverables of this Performance Work Statement. The technical information shall be reasonably complete and presented in a logical, readable manner. Text deliverables shall be provided in Microsoft Word 2016, Adobe Acrobat or compatible format. Deliverables will be accepted upon review and approval by the TOCOR.